DRUG REGULATORY AUTHORITY
OF PAKISTAN

Bio Study Rules, 2017

(As amended till September, 2026)

GOVERNMENT OF PAKISTAN
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)

BIO-STUDY RULES, 2017

Islamabad, the June 05th, 2018

N O T I F I C A T I O N

S.R.O. 697 (I)/2018. – In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to make the following rules, namely:-

1. Short title and commencement. - (1) These rules may be called the Bio-study Rules, 2017.

[1][(2) These rules shall apply to all contract research organizations or service providers, investigational products storage and management services, bio-analytical laboratories for clinical research, bio-availability and bio-equivalence study centers or organizations and healthcare facilities operating as clinical trial site in public or private sector, involved in clinical trials of therapeutic goods and bio-availability or bio-equivalence studies on human participants.]

(3) They shall come into force at once.

2. Definitions.– (1) In these rules, unless there is anything repugnant in the subject or context,-

(a) "Act" means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);

[2][(b) "adverse drug reaction" in case of,-

(i) pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic doses may not be established, means all noxious and unintended responses to a medicinal product related to any dose; and

(ii) marketed medicinal products, means a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function;]

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[1] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[2] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026

(c) "adverse event" or "AE" means any untoward medical occurrence in a patient or clinical investigation subject, to administered investigational product and which does not necessarily have a causal relationship with this treatment;

(d) "bio-availability" or "BA" means the therapeutically active fraction of administered drug that reaches the systemic circulation;

(e) "bio-equivalence "or "BE" means bio-equivalence phenomenon, according to which two medicinal products containing same pharmaceutical formulation and quantity of the same active ingredient, are considered bioequivalent if they are pharmaceutically equivalent and their bio-availabilities, in terms of rate and extent, after administration in the same molar dose, lie within acceptable predefined limits;

(f) "center" means bioavailability or bioequivalence studies center owned by public or private sector dully licensed by the DRAP;

(g) "clinical studies committee" or "CSC" means a committee constituted under rule 13;

[3][(ga) "clinical research" means any type of clinical research (interventional clinical trials or BA or BE studies) that involves human subjects and aims to determine the safety and efficacy of therapeutic goods (with or without placebo) and treatment regimens intended for human use;]

(h) "clinical trial" or "clinical study" means any investigation in human [4][participants] intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of an investigational product or to identify any adverse reactions to an investigational product or to study absorption, distribution, metabolism and excretion of an investigational product with the object of ascertaining its safety and efficacy;

[5][(i) contract research organization (CRO) or service provider (SP)" means a person or organization (commercial, academic or other) providing a service used by either the sponsor or the investigator to fulfil trial-related activities;]

[6][(j) "good clinical practice (GCP) guidelines" means International Council for Harmonisation (ICH)-GCP guidelines adopted by the Authority;]

(k) "independent ethics committee" or "IEC" means an independent body constituted of medical professionals and non-medical members, whose responsibility is to ensure the protection of the rights, safety and well-being of human [7][participants] involved in a trial and to provide public assurance of that protection by among other things, reviewing and approving or providing favourable opinion on the trial protocol, the suitability of the investigators, facilities, methods and material to be used in obtaining and documenting informed consent of the trial [8][participants];

(l) "ICH" means International Council for Harmonization;

(m) "informed consent" means a process by which a [9][participant] voluntarily confirms his willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the [10][participant]'s

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[3] Inserted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[4] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[5] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[6] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[7] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[8] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[9] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[10] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026

decision to participate. It is documented by means of a written, signed and dated informed consent form;

[11][(n) "institution" means any medical institution or health care facility in public or private entity or agency or medical or dental facility duly licensed or registered by the respective healthcare commission or healthcare regulatory authority, where clinical trials or any trial related activity or operations are proposed to be conducted;]

[12][(na) "investigational medical device (IMD)" means a medical device being assessed for clinical performance, effectiveness or safety in a clinical investigation;";

(nb) "investigational product (IP)" means investigational therapeutic goods or placebo being tested or used as a reference in a clinical research, including a product with a marketing authorization when used or assembled or formulated or packaged in a way different from the approved form or when used for an unapproved indication or when used to gain further information about an approved use;";

(nc) "investigational products storage and management services (IPSMS)" means an organization engaged in the storage, handling and distribution of investigational products, clinical trial materials or other regulated study-related supplies on contractual basis for sponsor in compliance with these rules and guidelines issued by the Authority and recognized standards, including good storage practices (GSP), good distribution practices (GDP), where applicable, to ensure the quality, integrity, and traceability of such products throughout the clinical research;]

(o) "IRB" means Institutional Review Board as [13][specified under the latest ICH-GCP guidelines].

(p) [14][Omitted]

(q) [15][Omitted]

(r) "trial subject".-means an individual who participates in a clinical trial, BA or BE study, either as a recipient of the investigational products or as a control.

[16][(ra) "referral site" means a healthcare facility or location that identifies and refers potential study participants to an approved clinical trial site and does not perform any trial-related procedures, except screening tests and administration of the informed consent form or any operation before administration or dispensing of IPs;";

(rb) "specialty clinics" means a healthcare facility duly licensed or registered by the respective healthcare commission or healthcare regulatory authority, that focus on specific area of medicine, medical condition or group of patients, rather than providing general or primary care, may be authorized to conduct interventional or post-marketing clinical trial within its specialty, in accordance with approved protocols, ethical standards, and guidelines

[11] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[12] Inserted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[13] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[14] Omitted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[15] Omitted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[16] Inserted vide S.R.O. 1446(I)/2026 dated 31st August, 2026

approved by the Authority. In the case of a specialty clinic, ethical approval obtained from the lead site and/or the National Bioethics Committee (NBC) or other designated body shall be deemed sufficient for the conduct of clinical trial at the specialty site; and]

(s) "trial [17][participant]" means an individual who participates in a clinical trial, BA or BE study, either as a recipient of the investigational products or as a control.

[18][(2) The words and expressions used but not defined herein shall have the same meanings as assigned to them in the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) or in the latest guidelines of the International Council for Harmonisation (ICH), standards of the International Organization for Standardization (ISO-14155) or guidelines duly issued by the Authority.]

[19][**3. Application for the grant of licence and fee thereof. -** (1) An application for grant of license for clinical trial site, BA or BE centre or bio-analytical laboratory, CRO or SP and IPSMS shall be made on Form-1, Form-2, Form-3 and Form-4 respectively addressed to the Division of Pharmacy Services.

(2) Every such application shall be accompanied with all the necessary records, information, documents, data as specified in the guidelines issued by the Authority and a non-refundable fee as notified under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022.

(3) The application shall be processed as per the guidelines issued by the Authority.

(4) Before issuance or renewal of license, the CSC shall satisfy itself that the conditions of license, as specified in the guidelines issued by the Authority, are complied with by the applicant or licensee.

(5) Certificate of license to act as BA and BE center, shall be issued on Form-9.

(6) Certificate of license to act as CRO/SP, clinical trial site or bio-analytical laboratory, as the case may be, shall be issued on relevant Form-10.

(7) Certificate of license to act as IPSMS, shall be issued on relevant Form-11.

(8) An applicant who is not satisfied with the decision of the CSC or the Chairman CSC, may file an appeal under rule 23.]

[20][**4. Conditions for license. –** A licensee shall comply with all the conditions specified in the guidelines issued by the Authority or such other conditions as required by the CSC, keeping in view the nature of the case.]

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[17] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[18] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[19] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[20] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026

5. Duration of license. - A license, issued in consequence of the application, shall, unless earlier suspended or cancelled, will remain in force for a period of three years from date of issuance.

[21]**[6. Renewal of license. -** A licencee may apply for renewal of the licence for clinical trial site, BA or BE centre or bio-analytical laboratory, CRO or SP and IPSMS as provided in Form-1, Form-2, Form-3 and Form-4 respectively, prior to the expiry of its validity period and not earlier than six months before such expiry, along with the prescribed renewal fee. Where an application for renewal is submitted after the expiry of the validity period, the licence may be renewed subject to payment of the full prescribed fee for each month.]

[22]**[7. Application for registration of clinical trial, BA or BE study.-** (1) Application for registration of clinical trial (Phase-I, II and III), clinical trial (Phase-IV), clinical trial or performance evaluation study of medical device, and BA or BE studies shall be made on Form-5, Form-6, Form-7 and Form-8 respectively addressed to the Division of Pharmacy Services.

(2) Every such application shall be accompanied with all the necessary records, information, documents, data and a non-refundable fee as notified under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022, along with the required documents or information as per Form-5, Form-6, Form-7 and Form-8 respectively.

(3) The received application shall be processed and scrutinized by the Division of Pharmacy Services for its completeness as per the prerequisites described as per Form-5, Form-6, Form-7 and Form-8 respectively and guidelines issued by the Authority.

(4) Certificate of registration of clinical trial, BA or BE study, as the case may be, shall be issued on Form-12,

(5) An applicant who is not satisfied with the decision of the CSC and/or the Chairman CSC may file an appeal under rule 23.]

[23]**[8. Conditions for registration of clinical trials and BA or BE studies.- (**1) The investigational product or trial material shall bear a label to state “caution: for investigational use only” and "Not for sale".

(2) The investigational product must have been produced by the manufacturer in compliance to the current good manufacturing practices.

(3) Quarterly progress report of results obtained during clinical trials shall be furnished to the Division of Pharmacy Services.

(4) Ethical criteria for the clinical research, as defined under ICH-GCP or WHO guidelines or the guidelines issued by the Authority must be fulfilled.

(5) Any serious adverse event (SAE) or suspected unexpected serious adverse reaction

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[21] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[22] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[23] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026

(SUSAR) shall be reported to the Division of Pharmacy Services, within the stipulated timelines as defined in the guidelines issued by the Authority.

(6) The final results of the clinical trial, BA or BE studies, shall be communicated to the Division of Pharmacy Services, at the completion of the clinical research.

(7) The sponsors and the investigators shall make themselves bound to permit access of any nominated officers of the Authority and/or GCP inspector, at reasonable times to copy and verify any records and reports relating to the clinical research.

(8) The progress report of clinical research shall contain sufficient information required to access the safety of participants of the clinical research.

(9) The clinical research shall not be conducted in a manner substantially different from the approved protocols and all deviations (which were necessary for wellbeing of trial participants) shall be reported to the NBC or its designated body nominated by the Chief Executive Officer, National Institute of Health (NIH) and the Authority.

(10) No amendments in the approved protocol of trial or study shall be made without seeking prior approval from CSC and the Chairman CSC, as the case may be.

(11) Any amendment or report of the clinical research, shall not contain any intrigue statement of material fact or omit material information required under these rules, ICH-GCP guidelines and guidelines issued by the Authority.

(12) The investigational product shall not be promoted or distributed for commercial purposes and quantities should be justified by the requirement of clinical research.

(13) The destruction or export of unused, expired or damaged investigational products, to the sponsor shall be carried out after seeking prior approval from the Chairman CSC, who shall nominate officers for the process of IP reconciliation and destruction of investigational products.

(14) On a notice by the Director, Division of Pharmacy Services, the sponsor shall provide written explanation or correction in writing, for any required information.

(15) The directions of ethics committee or IRB and NBC or its designated body nominated by the Chief Executive Officer, NIH shall strictly be complied with.

(16) Any information related to the clinical research that has an important bearing on the risk–benefit assessment of the IP or that would be sufficient to consider changes to the overall conduct of the clinical trial, requires to be communicated immediately to the Director, Division of Pharmacy Services.

(17) The CSC may terminate clinical trial (Phase-I, II and III) and the Chairman CSC may terminate clinical trial (Phase-IV) and BA or BE study registration, if the sponsor and investigator fails to;

(a) promptly investigate and inform the CSC of serious or unexpected adverse experiences in accordance with the latest ICH-GCP guidelines or the

guidelines issued by the Authority or fail to make any other report required under these rules;

(b) submit an accurate progress report of the investigations in accordance with the latest ICH-GCP guidelines or the guidelines issued by the Authority;

(c) comply with any other applicable requirements of these rules and the latest ICH-GCP guidelines or the guidelines issued by the Authority; or

(d) comply with such other condition as required by the CSC or Chairman CSC, keeping in view the nature of the case.

(18) The sponsor of a clinical trial may contract out the manufacture of IPs to a drug manufacturing licence (DML) holder possessing a valid good manufacturing practice (GMP) certificate issued by the Authority, strictly for the quantities specified in the application dossier and as authorized by the CSC or the Chairman CSC.

(19) A clinical trials and BA or BE studies registration holder shall comply with all the conditions specified in the guidelines issued by the Authority.]

[24][**9. Ethical clearance. -** It shall be mandatory for the applicants who are willing to conduct clinical research, to seek prior or in parallel ethical clearance or approval from the IRB of medical institutions or health care facility or university, where clinical trial site Center is situated and from NBC **or its designated body nominated by the Chief Executive Officer, NIH** in Pakistan.]

10. Labeling requirements for investigational products.- The immediate package of an investigational product intended for human use, shall bear a label with the statement "caution: For investigational use only" and "Not for Sale", prominently. The label or labeling of the investigational product shall not bear any statement that is false or misleading in any way and shall not represent that the investigational product is safe or effective for the purposes for which it is being investigated.

[25]**[11. Clinical trials monitoring and oversight. -** The Authority through its nominated experts or GCP inspectors, shall conduct scheduled or triggered inspections of the clinical trial, clinical trial sites and BA and BE study centres to monitor compliance of the approved study protocols and guidelines issued by the Authority.]

12. [26][Omitted]

[27][**13. Clinical studies committee. -** (1) The CSC shall consist of the following members, namely: -

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[24] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[25] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[26] Omitted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[27] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026

(i)	Director, Division of Pharmacy Services, DRAP	*ex-officio* Chairman
(ii)	Additional Director or Deputy Director, Division of Pharmacy Services, DRAP, (to be nominated by the Director Pharmacy Services), who shall be its *ex-officio* Secretary;	*ex-officio* Secretary/Member
(iii)	one expert from NBC or its designated body, to be nominated by the Chief Executive Officer, NIH;	Member
(iv)	one professor of pharmacology, having a basic degree in medicine, to be nominated by the Authority;	Member
(v)	one professor of pharmacology, having basic degree in pharmacy, to be nominated by the Authority;	Member
(vi)	one professor of pharmacy, having background of biopharmaceutics and at least ten years of experience, to be nominated by the Authority;	Member
(vii)	one clinician or physician or medical specialist having at least ten years of experience, to be nominated by the Authority;	Member
(viii)	one biostatistician, having background of designing and evaluating clinical studies with five years of experience or pharmaceutical professional having five years of experience in educational or professional services or practice of statistics, to be nominated by the Authority;	Member
(ix)	one epidemiologist or public health expert, possessing not less than ten years of relevant professional experience, to be nominated by the Authority;	Member
(x)	one clinical research expert, having basic degree in medicine, possessing not less than five years of relevant professional experience, to be nominated by the Authority;	Member
(xi)	one clinical research expert, having basic degree in pharmacy, possessing not less than five years of relevant professional experience, to be nominated by the Authority; and	Member
(xii)	one representative of Pakistan Pharmaceutical Manufacturers' Association and the Pharma Bureau each having fifteen years of experience and expertise of conducting clinical trials and BA or BE studies, to be nominated by the Authority, as observer.	Observer(s)

(2) The CSC may co-opt any expert as a member who shall not take part in voting.

(3) The CSC members, other than ex-officio members, shall hold office for a period of three years and may be eligible for re-nomination for one more time and shall continue to exercise their power and perform their functions until new members are nominated by the Authority.

(4) A CSC member, other than ex-officio members, may resign from his duties and in consequence thereof, the Authority may nominate a member in place of the member resigned for the remaining period.

(5) A simple majority of the total membership shall constitute the quorum for a meeting of the CSC and in case of equality of votes, the Chairman shall have a casting vote.

(6) The CSC and the Chairman, CSC shall exercise powers and perform functions as provided below, namely: -

(a) the CSC shall grant, reject or suspend registration of a clinical trials (Phase-I, II and III only). The Chairman, CSC shall take decisions (grant, reject or suspend registration) on Phase-IV clinical trials and BA or BE study;

(b) the CSC may grant, reject or suspend a license to clinical trial sites, BA or BE studies center, bio-analytical laboratories, IPSMS and CRO/SP;

(c) the Chairman, CSC may grant extension in trial duration of Phase-I, II, III and IV clinical trials, and BA or BE studies, keeping in view the public interest and within the stipulated timelines defined in the guidelines approved by the Authority;

(d) the CSC shall grant renewal of licenses under these rules;

(e) the CSC or the Chairman, CSC, as the case may be, may grant permission for the manufacture of IPs by a drug manufacturing licence (DML) holder possessing a valid GMP certificate issued by the Authority:

Provided that such DML holder has a valid manufacturing contract with the sponsor of the clinical trial duly submitted to the Division of Pharmacy Services and subject to prior approval of the clinical trial under these rules;

(f) the CSC may constitute a sub-committee for the performance of any special task;

(g) the CSC and the Chairman, CSC may co-opt any national or international subject related expert person having minimum of five years experience in the relevant field for review or advice on any particular matter under consideration;

(h) the meetings of the CSC may be held with prior approval of the Chairman, CSC or at any time as may be required on the direction of Chairman, who may at any time call a meeting within a period of fifteen days if there is any urgent matter for its consideration;

(i) the CSC shall also consider relevant clinical trial decisions, reports or other information from reference regulatory authorities for reliance as per guidelines issued by the Authority:

Provided that any application for registration of clinical trial shall not undergo in the assessment process, if the same at any stage, has already been rejected, suspended or put on hold by other participating countries of the trial due to any reason, in reference regulatory authorities and shall be rejected, suspended or put on hold during the process of screening, as the case may be;

(j) the CSC may delegate any of its powers to Chairman, CSC in writing with appropriate justification; and

(k) the CSC shall fix the responsibility of offences through a speaking order after examining the case referred to it by the GCP inspector or nominated officers or experts and sanction the prosecution before referring the case to the Drug Courts.]

[28][**14. Prohibitions. -** (1) No one can operate as clinical trial sites, BA or BE studies center, bio-analytical laboratories, IPSMS and CRO/SP, in Pakistan without prior approval of the licence from the CSC under these rules.

(2) No clinical trial and BA or BE studies shall be conducted except with the prior approval of the registration by the CSC or the Chairman, CSC, as the case may be.

(3) No clinical trial or study and BA or BE studies shall be conducted after the expiry of the period provided in the registration letter or any extension thereof except with the prior permission of the CSC or the Chairman, CSC as the case may be, in accordance with the conditions as specified under the guidelines issued by the Authority.

(4) No proceeding shall be continued even within the extended period under intimation to the CSC, if the ongoing trial is reported or found to be in contravention of any provision of these rules for getting authorization on the basis of false submissions.

(5) No clinical research shall be allowed to continue if the conditions to the approved protocol were violated in terms of variation without permission of the CSC.]

15. GCP, GLP and BA or BE guidelines.- The DRAP shall adapt the [29][latest] ICH–GCP guidelines and also the GLP, BA or BE guidelines [30][, relevant ISO-standard (for medical devices trials)] as per WHO, ICH and other international standards, which describe the criteria for the conduct of clinical trials and BA or BE studies following good clinical practice and good laboratory practice principles:

Provided that the DRAP shall revise or upgrade these guidelines from time to time, in compliance with the international standards.

[31][**16. Cancellation or suspension of license and registration.-** (1) If the license holder or clinical trial, BA or BE study registration holder, as the case may be, does not comply with any of the provisions of the Act, the Drugs Act, 1976 (XXXI of 1976) and rules made and

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[28] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[29] Inserted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[30] Inserted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[31] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026

guidelines issued thereunder, the CSC, after giving an opportunity of hearing, may cancel or suspend the license or registration, as the case may be, for such a period as it thinks fit, by an order in writing, stating the reasons thereof.

(2) If at any time, for safety reason or any other ground, a clinical trial is withdrawn or suspended anywhere in the world, the sponsor or its representative or PI in Pakistan shall, forthwith, inform Division of Pharmacy Services, all participating investigators and all reviewing institutional review boards and NBC or its designated body, nominated by NIH, together with the reasons for such withdrawal or suspension, within seven calendar days. The inventories of the IPs shall be maintained and its safe custody shall be ensured.

(3) The CSC on having information with regard to the safety of the participants or any other ground, after giving an opportunity of personal hearing to the registration holder, may at its own motion withdraw or suspend the clinical trial.

(4) The stocks of the IPs so recovered or recalled shall be returned to the sponsor or otherwise disposed of, as the CSC or the Chairman, CSC may allow and deems fit.]

17. Complaint handling.- The CSC, upon receiving of compliant and after having inquiry into the matter, is satisfied, that the public interest so requires, may take action under rule 13 against license holder or [32][registration] holder, as the case may be.

18. [33][Omitted]

19. [34][Omitted]

20. Clinical trial registry.- (1) Clinical trial registry means an official catalog, containing publicly accessible record of approved clinical trials.

(2) DRAP shall maintain clinical trial registry for approved clinical trials involving [35][therapeutic goods], being conducted in Pakistan.

(3) The clinical trial registry of Pakistan shall be a primary registry, which may in future, be linked to the registry network of the International clinical trials registry platform of the WHO (WHO-ICTRP). It shall be a not-for-profit registry, with free and open access to researchers, clinicians, and the general public.

[36][**21. Participants registry.-** A verifiable record of the healthy participants shall be maintained to stop duplicate enrolment, specifically in Phase-I clinical trial and BA or BE studies, during the IP washout period. The participant's identification shall be a closed information and submitted to the Division of Pharmacy Services, if directed.]

22. [37][Omitted]

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[32] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[33] Omitted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[34] Omitted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[35] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[36] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[37] Omitted vide S.R.O. 1446(I)/2026 dated 31st August, 2026

[38][**23. Appeal**.– A person who is aggrieved by the decision of the CSC or Chairman, CSC, may file an appeal in writing, within sixty days, to the Authority.]

[39][**24. Power to amend Forms.-** The Authority may, on the recommendation of the Clinical Studies Committee, amend Forms so as to omit any entry therefrom, add any entry thereto or amend any entry therein.]

[40][

Form–1

[See rule 3]

Application for the grant/renewal of license to act as clinical trial site

I …… holding CNIC number……..... of (Name of Hospital/Institute) …… hereby apply for the grant/renewal of license to act as clinical trial site situated at …… …….

2. Type of the Clinical Trial Site meant for (encircle one): -

Generalized Clinical Trial Site / Clinical Trial Unit			**Trial Specific/specialized Clinical Trial Site**		
i.	Phase I		i.	Trial-specific site for the Clinical Trial titled. "……".	
ii.	Phase II				
iii.	Phase III		ii.	Specialty Clinic	
iv.	Phase IV				

* In the generalized category, multiple phase selection is allowed, wherein specialized/trial-specific, only one category can be selected.

** For a generalized Phase-I site, details regarding the following facilities are required with the application:

- Trial Unit should be developed in a Tertiary Care Health Facility,
- Controlled boarding & lodging facilities for volunteers along with a recreational area,
- PK/PD Sampling and logistic facilities,
- Clinical Pathology Lab Services with refrigerated centrifuges, Biosafety cabinets, Sample aliquoting rooms with limited access, −20°C and −80°C freezers with alarms & backup.
- 24/7 Medical Coverage of ICU/ER Facility along with research staff (PI, Physicians, Pharmacists, Nurses and emergency trained staff etc.)
- Crash cart with defibrillator, emergency injectable, oxygen supply
- Staff trained in BLS, ACLS, and anaphylaxis management.

3. I enclose: -

(a) Particulars regarding the legal status of the applicant and/or site i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm

[38] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[39] Inserted vide S.R.O. 1446(I)/2026 dated 31st August, 2026
[40] Substituted vide S.R.O. 1446(I)/2026 dated 31st August, 2026

the names and addresses of its partners and in the case of company the name and address of the company and its directors), along with relevant documentary evidence and licence form relevant Healthcare Commission.

(b) Details of site premises, along with layout plan.
(c) Details of the section-wise equipment and machinery required for the applied category of Clinical Trial Site.
(d) Names and qualifications of the research staff, along with the organogram of the organization.
(e) Details of the allied facilities associated with the trial site, including ambulatory services, emergency handling, etc., as required for the applied category of Clinical Trial Site.
(f) Copy of licence. (If applied for renewal)

UNDERTAKING

I……. (Head of Hospital/Institute or authorized person) hereby undertake / certify that the contents stated above are correct to the best of my knowledge and belief.

Signature

Name of the applicant
Designation:
Email address:
Contact number:

Date:……

Form-2

[See rule 3]

Application for the grant/renewal of license to act as BA/BE center or Bio-analytical laboratory

I …… holding CNIC number……..... of (Name of organization) …… hereby apply for the grant/renewal of license to act as BA/BE center or Bio-analytical laboratory, situated at ……..……

2. Type of the site meant for (encircle one): -
   (i) Bio-equivalence and Bio-availability studies
   (ii) Bio-analytical laboratory

3. I enclose: -
   (a) Particulars regarding the legal status of the applicant i.e. in case of proprietorship, the names of proprietors and their addresses, in the case of firm the names and addresses of its partners and in the case of company the name and address of the company and its directors, along with relevant documentary evidence.
   (b) Details of premises, including layout plan.
   (c) Details of the section-wise equipment and machinery required for the Pharmacokinetic studies, analytical or bio-analytical assays.
   (d) Names and qualifications of the staff involved in Pharmacokinetic studies, analytical or bio-analytical assays, along with the organogram of the organization.
   (e) Details of the allied facilities associated with the BA/BE center / Bio-analytical laboratory, including ambulatory services, emergency handling etc.
   (f) Copy of licence. (If applied for renewal)

UNDERTAKING

I……. (Head of organization or authorized person) hereby undertake / certify that the contents stated above are correct to the best of my knowledge and belief.

Signature

Name of the applicant
Designation:
Email address:
Contact number:

Date:……

Form –3

[See rule 3]

Application for the grant/renewal of license to act as Contract Research Organization (CRO) / Service Provider (SP)

I …… holding CNIC number……..... of (Name of organization)…….…… hereby apply for the grant/renewal of license to act as CRO / Service Provider (SP), situated at ……

2. I enclose: -

(a) Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the names and addresses of its partners and in the case of company the name and address of the company and its directors), along with relevant documentary evidence.
(b) Details of premises, along with layout plan of the CRO / Service Provider.
(c) Details of the section wise equipment and machinery required to operate as a CRO / Service Provider.
(d) Names and qualifications of the staff (division-wise), required to operate as CRO / Service Provider, along with the organogram of the organization.
(e) Details of other facilities associated with the CRO / Service Provider.
(f) Copy of licence. (If applied for renewal)

UNDERTAKING

I ……. (Head of organization or authorized person) hereby undertake / certify that the contents stated above are correct to the best of my knowledge and belief.

Signature

Name of the applicant
Designation:
Email address:
Contact number:

Date:……

Form–4

[See rule 3]

Application for the grant/renewal of license to act as Investigational Products Storage and Management Services (IPSMS)

I …… holding CNIC number……..... of (Name of organisation) ……hereby apply for the grant/renewal of license to act as Investigational Products Storage and Management Services (IPSMS), situated at ……..……...

2. I enclose: -

(a) Particulars regarding the legal status of the applicant, i.e. in case of proprietorship, the names of proprietors and their addresses, in the case of firm the names and addresses of its partners and in the case of company the name and address of the company and its directors, along with relevant documentary evidence.

(b) Details of premises, including layout plan (i.e. Quarantine IP, released IP, IP cold chain, returns, IP expired or destruction) of the storage facility and office.

(c) Details of the following:

- Environmental Monitoring and Control System: Temperature / Humidity monitoring, alarm system, backup system),
- Normal/cold storage details: (2–8°C, –20°C, Ultra Low Temperature ULT, ambient)
- Security System**:** Restricted access control, CCTV, tamper-proof system
- Quality Management System**:** SOPs and guidelines for IPs Chain of custody, accountability and reconciliation, CAPA, recalls, deviations record and reporting
- Certifications: ISO, GSDP etc. (optional)

(d) Details of the section-wise equipment and machinery required to operate as an IPSMS.

(e) Names and qualifications of the qualified staff (division-wise) required to operate as IPSMS, along with the organogram of the organization.

(f) Details of other facilities associated with the IPSMS and emergency handling etc.

(g) Copy of previously granted licence. (If applied for renewal)

UNDERTAKING

I……. (head of organization/authorized person) hereby undertake/certify that the contents stated above are correct to the best of my knowledge and belief.

Signature

Name of the applicant
Designation:
Email address:
Contact number:

Date:

Form – 5

[See rule 6]

Application for registration of clinical trial (Phase-I, II and III) on therapeutic goods (except Medical Devices)

I ……holding CNIC number……...of (Name of Hospital/Institute) …….. hereby apply for registration of clinical trial, titled "……"

2. The details regarding the trial, sponsor and responsible party are as under:

i. **Sponsor:** <Name with address of the trial/study Sponsor(s)>.

ii. **Collaborators** (If applicable): <Name with address(s) of the trial/study collaborators>.

iii. **Purpose of trial:** <Briefly explain the purpose of the trial as mentioned in the attached protocol>

iv. **Phase of the trial:** <Mention the Phase of the applied trial>

v. **Duration of the trial: <** Mention the complete duration of the applied trial>

vi. **Details of IPs need to be imported/procured for the trial, along with justification:**

IPs name/ code	Molecule/active ingredients	Strength	Pack Size	Manufacturer of IP	No. of participants	Dose	Frequency	Total
Packaging site with address: <If any/other than Sponsor/Manufacturer>								

vii. **Source(s) of IPs and Comparator/Ancillary products/Auxiliary items:**

- <Name and complete address of IPs manufacturer(s)>
- <Name and complete address of Placebo/Comparator(s) manufacturer(s) (if any)>.
- <Name and complete address of Ancillary products / Auxiliary items manufacturer(s) (if any)>.

viii. **Wastage and Damage (….) % (along with its justification):**

- Active: XXX * XX% = XXX; Total Import Quantity: XXX + XXX = XXX
- Placebo/Comparator: XXX * XX% = XXX; Total Import Quantity: XXX + XXX = XXX

ix. **Details of Auxiliary/Ancillary items (Lab kits etc.) need to be imported/procured for the trial, along with justification:**

Name of item	Description of Item	Manufacturer	Total
Packaging site with address: <If any/other than Sponsor/Manufacturer>			

x. **Number of participants to be enrolled: <number of participants to be enrolled>** Globally (in case of MRCT) and/or **<number of participants to be enrolled>** in Pakistan, also include details regarding age group and gender.

xi. **Anticipated cost of the project:** <USD or any other currency mentioned in the

application dossier>.

xii. Study design and details: (As per attached protocol):

Study type	
Estimated Enrollment:	
Allocation:	
Intervention Model:	
Masking:	
Estimated Study Start Date:	
Estimated Primary Completion Date:	
Estimated Study Completion Date:	

xiii. Details regarding primary and secondary objective(s) and end point of the trial/study:

- Primary Outcome Measures/objective(s):
  i. ABC
  ii. XYZ
- Secondary Outcome Measures(s):
  i. abc
  ii. xyz
- Any other outcomes of special interest (if any):
  i. abc
  ii. xyz
- Study/trial end point:

3. <Details regarding proposed Clinical Trial Sites with their scope, validity and role>

S.No.	Name and Licence No. of the proposed Site(s)	Validity status of the site	Scope of the applied trial site	Role of the Site (Trial or Referral Site)
i.				
ii.				
iii.				
iv.				
v.				

4. Required documents for the application dossier are as under:

S. No.	Description of Document	
1	Application on prescribed Form-5 along with an undertaking on affidavit	Provide as attachment
2	Prescribed processing fee challan	Provide as attachment
3	Investigator Brochure (s) along with its summary/synopsis	IB Edition/Version No. ……., Dated…… Provide as attachment
4	Final protocol along with its summary/synopsis	Protocol Edition/Version No. ……..….., Dated…… Provide as attachment
5	• Pre-clinical/clinical safety studies for Phase-I • Phase-I Trials results for Phase-II • Phase-I and II trial results for Phase-III	(As required for applied Phase of the trial)> Provide as attachment

6	Serious Adverse Event Reporting Form	Provide as attachment
7	Informed consent and participant information sheet (In Urdu & English)	ICF Edition/Version No. and Dated:… Provide as attachment
8	List of participating countries	<Mention names of participating countries as described in application dossier or in trial registry (if any)> Provide as attachment
9	Enlistment status of trial on any international trial registry (if any)	Link(s) of Clinical Trial Registry(ies) • •
10	Details and quantity of IPs and other Ancillary/Auxiliary items to be imported on Form 4 under the Drugs (Import and Export) Rules, 1976, and/or; The details and quantities of Investigational Products (IPs), including any ancillary or auxiliary items, to be manufactured by a Drug Manufacturing Licence (DML) holder possessing a valid Good Manufacturing Practice (GMP) certificate, relevant to the applicable dosage-form section, issued by the Drugs Regulatory Authority of Pakistan, and shall be manufactured only after approval by the Clinical Studies Committee or the Chairman thereof, as the case may be.	Provide as attachment
11	Institutional Review Board (IRB)/Ethics Review Committee (ERC) approval of the trial along with IRB/ERC Notification with complete composition of IRB/ERC committee (as per ICH-GCP and/or DRAP guidelines template for IRB/ERC)	Provide as attachment
12	Approval of the National Bio-ethics Committee (NBC) **or its designated body**	Provide as attachment
13	Provide the evidence of clinical expertise and relevancy of PI/Site PI with reference of trial.	(CVs of PI, Co-PI's, Site-PI and other research team) Provide as attachment
14	GMP certificate (of manufacturer) and/or equivalent ISO certificate (for medical devices), along with Certificate of Analysis of the investigational product.	Provide as attachment
15	Evidence of market authorization/registration in the country of origin (in case of registered IPs only).	Provide as attachment
16	Manufacturing Licence issued by the DRAP (in case of IPs manufactured by a Pakistani manufacturer)	Provide as attachment

17	No. of participants to be enrolled in each center.	<Details regarding bifurcation of participant's enrolment at each CTS> i. XXX participant's will be enrolled at Site 1. ii. XXX participant's will be enrolled at Site 2. iii. XXX participant's will be enrolled at Site 3. Total XX participant's to be enrolled in Pakistan. Total XXX participant's to be enrolled globally (In case of /MRCT). Provide as attachment
18	Name of Sponsor's nominated Contract Research Organization / Service Provider duly approved by DRAP	Please provide the details of assigned tasks, with a copy of the contract and/or letter from the Sponsor (If any), along with details of trial monitors and Clinical Research Associate (CRAs)
19	Name of Sponsor's nominated DRAP-approved Investigational Products Storage & Management Services (IPSMS)	Provide details of assigned tasks, with a copy of the contract and/or letter from the Sponsor (If any)
20	Sample label of the investigational product as per the latest ICH-GCP/DRAP Guidelines.	Provide as attachment
21	Details regarding trial participants insurance.	Sponsor and/or PI shall attach insurance details.

5. Any other documents attached along with the application:
For example:

i. <Investigator Instructions Manual>
ii. <Laboratory Manual>
iii. <Material Transfer Agreement>
iv. <Any other documents etc.>

UNDERTAKING

I ……. (Principal Investigator of applied trial titled, "……"), hereby undertake/certify that the contents stated above are correct to the best of my knowledge and belief.

Signature

Name of the Principal Investigator
Designation:
Email address:
Contact number:

Date:…….

Form – 6

[See rule 6]

Application for registration of Interventional clinical trial (Phase-IV) on therapeutic goods (except Medical Devices)

I ……holding CNIC number……...of M/s …….. hereby apply for registration of clinical trial, titled "……..……..…".

2. The details regarding the trial, sponsor and responsible party are as under:

i. Sponsor: <Name with address of the trial/study Sponsor(s)>.

ii. Collaborators: (If applicable): <Name with address(s) of the trial/study collaborators>.

iii. Purpose of trial: <Briefly explain the purpose of the trial as mentioned in the attached protocol>

iv. Phase of the trial: <Mention the Phase of the applied trial>

v. Duration of the trial: < Mention the complete duration of the applied trial>

vi. Details of IPs need to be imported/procured for the trial, along with justification:

IPs name/ code	Molecule/active ingredients	Strength	Pack Size	Manufacturer of IP	No. of participants	Dose	Frequency	Total
Packaging site with address: <If any/other than Sponsor/Manufacturer>								

vii. Source(s) of IPs and Comparator/Ancillary products/Auxiliary items:

- <Name and complete address of IPs manufacturer(s)>
- <Name and complete address of Placebo/Comparator(s) manufacturer(s) (if any)>.
- <Name and complete address of Ancillary products / Auxiliary items manufacturer(s) (if any)>.

viii. Wastage and Damage (….) % (along with its justification):

- Active: XXX * XX% = XXX; Total Import Quantity: XXX + XXX = XXX
- Placebo/Comparator: XXX * XX% = XXX; Total Import Quantity: XXX + XXX = XXX

ix. Details of Auxiliary/Ancillary items (Lab kits etc.) need to be imported/procured for the trial, along with justification:

Name of item	Description of Item	Manufacturer	Total
Packaging site with address: <If any/other than Sponsor/Manufacturer>			

x. Number of participants to be enrolled: <number of participants to be enrolled> Globally (in case of MRCT) and/or **<number of participants to be enrolled>** in Pakistan, also include details regarding age group and gender.

xi. Anticipated cost of the project: <USD or any other currency mentioned in the

application dossier>.

xii. Study design and details: (As per attached protocol):

Study type	
Estimated Enrollment:	
Allocation:	
Intervention Model:	
Masking:	
Estimated Study Start Date:	
Estimated Primary Completion Date:	
Estimated Study Completion Date:	

xiii. Details regarding primary and secondary objective(s) and end point of the trial/study:

- Primary Outcome Measures/objective(s):
  i. ABC
  ii. XYZ
- Secondary Outcome Measures(s):
  i. abc
  ii. xyz
- Any other outcomes of special interest (if any):
  i. abc
  ii. xyz
- Study/trial end point:

3. <Details regarding proposed Clinical Trial Sites with their scope, validity and role>

S.No.	Name and Licence No. of the proposed Site(s)	Validity status of the site	Scope of the applied trial site	Role of the Site (Trial or Referral Site)
i.				
ii.				
iii.				
iv.				
v.				

4. Required documents for the application dossier are as under:

S. No.	Description of Document	
1	Application on prescribed Form-6 along with an undertaking on affidavit	Provide as attachment
2	Prescribed processing fee challan	Provide as attachment
3	Investigator Brochure (s) along with its summary/synopsis or SmPC	IB Edition/Version No. ……., Dated…… Provide as attachment
4	Final protocol along with its summary/synopsis	Protocol Edition/Version No. ……..….., Dated…… Provide as attachment
5	Phase-III trial results	(As required for applied Phase of the trial)> Provide as attachment
6	Serious Adverse Event Reporting Form	Provide as attachment

7	Informed consent and participant information sheet (In Urdu & English)	ICF Edition/Version No. and Dated:… Provide as attachment
8	List of participating countries	<Mention names of participating countries as described in application dossier or in trial registry (if any)> Provide as attachment
9	Enlistment status of trial on any international trial registry (if any)	Link(s) of Clinical Trial Registry(ies) • •
10	Details and quantity of drug / IPs and other Ancillary/Auxiliary items to be imported on Form 4 under the Drugs (Import and Export) Rules, 1976, and/or; The details and quantities of Investigational Products (IPs), including any ancillary or auxiliary items, to be manufactured by a Drug Manufacturing Licence (DML) holder possessing a valid Good Manufacturing Practice (GMP) certificate, relevant to the applicable dosage-form section, issued by the Drugs Regulatory Authority of Pakistan, and shall be manufactured only after approval by the Clinical Studies Committee or the Chairman thereof, as the case may be.	Provide as attachment
11	Institutional Review Board (IRB)/Ethics Review Committee (ERC) approval of the trial along with IRB/ERC Notification with complete composition of IRB/ERC committee (as per ICH-GCP and/or DRAP guidelines template for IRB/ERC)	Provide as attachment
12	Approval of the National Bio-ethics Committee (NBC) **or its designated body**	Provide as attachment
13	Provide the evidence of clinical expertise and relevancy of PI/Site PI with reference of trial.	(CVs of PI, Co-PI's, Site-PI and other research team) Provide as attachment
14	GMP certificate (of manufacturer) and/or equivalent ISO certificate (for medical devices), along with Certificate of Analysis of the investigational product.	Provide as attachment
15	Evidence of market authorization/registration in the country of origin (in case of registered IPs only).	Provide as attachment

16	Manufacturing Licence issued by the DRAP (in case of IPs manufactured by a Pakistani manufacturer)	Provide as attachment
17	No. of participants to be enrolled in each center.	<Details regarding bifurcation of participant's enrolment at each CTS> i. XXX participant's will be enrolled at Site 1. ii. XXX participant's will be enrolled at Site 2. iii. XXX participant's will be enrolled at Site 3. Total XX participant's to be enrolled in Pakistan. Total XXX participant's to be enrolled globally (In case of /MRCT). Provide as attachment
18	Name of Sponsor's nominated Contract Research Organization / Service Provider duly approved by DRAP	Please provide the details of assigned tasks, with a copy of the contract and/or letter from the Sponsor (If any), along with details of trial monitors and Clinical Research Associate (CRAs)
19	Name of Sponsor's nominated DRAP's approved Investigational Products Storage & Management Services (IPSMS)	Provide details of assigned tasks, with a copy of the contract and/or letter from the Sponsor (If any)
20	Sample label of the investigational product as per the latest ICH-GCP/DRAP Guidelines.	Provide as attachment
21	Details regarding trial participants insurance.	Sponsor and/or PI shall attach insurance details.

6. Any other documents attached along with the application:
For example:

i. <Investigator Instructions Manual>
ii. <Laboratory Manual>
iii. <Material Transfer Agreement>
iv. <Any other documents etc.>

UNDERTAKING

I ……. (Principal Investigator of applied trial titled, "……"), hereby undertake / certify that the contents stated above are correct to the best of my knowledge and belief.

Signature

Name of the Principal Investigator
Designation:
Email address:
Contact number:

Date:…….

Form – 7

[See rule 6]

Application for registration of clinical trial/performance evaluation study of medical devices

I ……holding CNIC number……...of M/s …….. hereby apply for registration of clinical trial, titled "……" hereby apply for registration of clinical trial/performance evaluation study, titled "……..…….…….……..…….."

2. The details regarding the trial/performance evaluation study, sponsor and responsible party are as under:

   i. **Sponsor:** <Name with address of the trial/study Sponsor(s)>.
   ii. **Collaborators**: (If applicable): <Name with address(s) of the trial/study collaborators>.
   iii. **Purpose of trial:** <Briefly explain the purpose of trial as mentioned in the attached protocol>
   iv. **Duration of the trial: <** Mention the complete duration of the applied trial>
   v. **Details of Investigational Medical Device(s) (IMDs) need to be imported/procured for the trial/study, along with justification:**

IMDs Description	Make/model	Class of device	Manufacturer	No. of devices required	Total
Packaging site with address: <If any/other than Sponsor/Manufacturer>					

   vi. **Details regarding Comparator Device and Ancillary products/Auxiliary items required for the study (if any):**
   - <Name and complete address of IPs manufacturer(s)>
   - <Name and complete address of Comparator(s) manufacturer(s) (if any)>.
   - <Name and complete address of Ancillary products / Auxiliary items manufacturer(s) (if any)>.

   vii. **Wastage and Damage (….) % (along with its justification):**
   - IMD: XXX * XX% = XXX; Total Import Quantity: XXX + XXX = XXX
   - Comparator Device (if any): XXX * XX% = XXX; Total Import Quantity: XXX + XXX = XXX

   viii. **Details of Auxiliary/Ancillary items (Lab kits etc.) need to be imported/procured for the trial, along with justification:**

Name of item	Description of Item	Manufacturer	Total
Packaging site with address: <If any/other than Sponsor/Manufacturer>			

   ix. **Number of participants to be enrolled: <number of participants to be enrolled>**

Globally (in case of MRCT) and/or **<number of participants to be enrolled>** in Pakistan, also include details regarding age group and gender.

x. **Anticipated cost of the project:** <USD or any other currency mentioned in the application dossier>.

xi. **Study design and details:** (As per attached protocol):

Study type	
Estimated Enrollment:	
Allocation:	
Intervention Model:	
Masking:	
Estimated Study Start Date:	
Estimated Primary Completion Date:	
Estimated Study Completion Date:	

xii. Details regarding primary and secondary objective(s) and end point of the trial/study:

- Primary Outcome Measures/objective(s):
  i. ABC
  ii. XYZ
- Secondary Outcome Measures(s):
  i. abc
  ii. xyz
- Any other outcomes of special interest (if any):
  i. abc
  ii. xyz
- Study/trial end point:

3. <Details regarding proposed Clinical Trial Sites with their scope, validity and role>

S.No.	Name and Licence No. of the proposed Site(s)	Validity status of the site	Scope of the applied trial site	Role of the Site (Trial or Referral Site)
i.				
ii.				
iii.				
iv.				
v.				

2. Required documents for the application dossier are as under:

S. No.	Description of Document	
1	Application on prescribed Form-7 (A) along with an undertaking on affidavit	Provide as attachment
2	Prescribed processing fee challan	Provide as attachment
3	Phase of trial.	Select one of the following: Phase-I ☐ Phase-III ☐ Phase-II ☐ Phase-IV ☐ Non-Phase Trial/Medical Device performance evaluation trial ☐

4	Device Investigator's Brochure (DIB) or Investigator Brochure (s) along with its summary/synopsis	DIB Edition/Version No. ……., Dated…… Provide as attachment
5	Final protocol along with its summary/synopsis	Protocol Edition/Version No. ……..…., Dated……..…… Provide as attachment
6	Pre-clinical/clinical safety studies and or performance evaluation studies (If any)	<As required for applied Phase of the trial)> Provide as attachment
7	Serious Adverse Event Reporting Form	Provide as attachment
8	Informed consent and participant information sheet (In Urdu & English)	ICF Edition/Version No. and Dated:… Provide as attachment
9	List of participating countries (If any)	<Mention names of participating countries as described in application dossier or in trial registry (if any)> Provide as attachment
10	Enlistment status of trial on any international trial registry (If any)	Link(s) of Clinical Trial Registry(ies) • •
11	Details regarding number of IPs (Medical Devices) and other Ancillary/Auxiliary items to be imported on Form-9 under the Medical Devices Rules, 2017. The details and quantities of Investigational Products (IMDs), including any ancillary or auxiliary items, to be manufactured by a Medical Devices Manufacturing Licence holder issued by Medical Devices Board, possessing a valid Good Manufacturing Practice (GMP) or its equivalent certificate, relevant to the applicable dosage-form section, issued by the Drugs Regulatory Authority of Pakistan, and shall be manufactured only after approval by the Clinical Studies Committee or the Chairman thereof, as the case may be.	Provide as attachment
13	Institutional Review Board (IRB)/Ethics Review Committee (ERC) approval of the trial along with IRB/ERC Notification with complete composition of IRB/ERC committee (as per ICH-GCP and/or DRAP guidelines template for IRB/ERC)	Provide as attachment
14	Approval of the National Bio-ethics Committee (NBC) or its designated	Provide as attachment

	body.	
15	Provide the evidence of clinical expertise and relevancy of PI/Site PI with reference of trial.	(CVs of PI, Co-PI's, Site-PI and other research team) Provide as attachment
16	GMP/ISO 13485 certificate of medical device manufacturer, along with free sale certificate/Certificate of Free Sale (CFS) and/or CE marking of the IMDs.	Provide as attachment
17	Evidence of market authorization/registration/enlistment in the country of origin (in case of registered IMDs only).	Provide as attachment(If applicable)
18	Copy of registration letter (if registered in Pakistan) (in case of registered IMDs only).	Provide as attachment
19	Manufacturing Licence issued by the DRAP (in case of IMDs manufactured by a Pakistani manufacturer)	Provide as attachment
20	No. of participants to be enrolled in each center.	<Details regarding bifurcation of participant's enrolment at each CTS> iv. XXX participant's will be enrolled at Site 1. v. XXX participant's will be enrolled at Site 2. vi. XXX participant's will be enrolled at Site 3. Total XX participant's to be enrolled in Pakistan. Total XXX participant's to be enrolled globally (In case of /MRCT). Provide as attachment
21	Name of Sponsor's nominated Contract Research Organization / Service Provider duly approved by DRAP	Please provide the details of assigned tasks, with a copy of the contract and/or letter from the Sponsor (If any), along with details of trial monitors and Clinical Research Associate (CRAs)
22	Name of Sponsor's nominated DRAP's approved Investigational Products Storage & Management Services (IPSMS)	Provide details of assigned tasks, with a copy of the contract and/or letter from the Sponsor (If any)
23	Sample label of the investigational medical device as per the latest ISO-14155 and/or DRAP Guidelines.	Provide as attachment
25	Details regarding trial participants insurance.	Sponsor and/or PI shall attach insurance details.

4. Any other documents attached along with the application:

For example:

i. <Investigator Instructions Manual>
ii. <Laboratory Manual>
iii. <Material Transfer Agreement>
iv. <Any other documents etc.>

UNDERTAKING

I ……. (Principal Investigator of applied trial titled, "……"), hereby undertake / certify that the contents stated above are correct to the best of my knowledge and belief.

Signature

Name of the Principal Investigator
Designation:
Email address:
Contact number:

Date:……

Form – 8

[See rule 6]

Application for registration of bioequivalence or bioavailability study

I ……holding CNIC number……...of M/s ……..hereby apply for registration of BA or BE Study, titled "…….……".

2. The details regarding BA/BE Study, Sponsor and responsible party, etc., are as under:

i. **Sponsor:** (Details regarding the Sponsor of the study)
ii. **Funding Source**: (Details of funder)
iii. **Title of BA or BE Study:** (Title of the study as mentioned in the protocol)
iv. **Purpose of the study: (**Briefly explain the purpose of the trial as mentioned in the attached protocol).
v. **Duration of the study: <** Mention the complete duration of the applied study>
vi. **Principal Investigator:** (Name and details of PI)
vii. **Co-Principal Investigator:** (Name and details of Co-PI)
viii. **Number of participants to be enrolled in the study**: (Details regarding the number of participants along with any specified conditions, if any).
ix. **Details of IPs (test and reference products)**: Need to be imported/procured for the study, along with justification:

IPs brand/trade name		**Active ingredients**	**Generic name**	**Chemical code**	**INN name**	**Pack Size**	**Manufacturer**
Test product							
Reference product							

Quantities of Test & Reference product required for the study:

A. For Test Product:
a. Sample Size: (Number of study participants)
b. Investigational Product for Clinical Phase: (required quantity)
c. Investigational Product required for testing phase and quarantine: (Required quantity)
d. Additional quantities required along with justification: (Required quantity)
e. Total quantity of IPs (test product): (Required quantity)
Manufactured by: (Manufacturer name along with address)

B. For Reference Product:
a. Sample Size: (Number of study participants)
b. Investigational Product for Clinical Phase: (required quantity)
c. Investigational Product required for testing phase and quarantine: (Required quantity)
d. Additional quantities required along with justification: (Required quantity)
e. Total quantity of IPs (test product): (Required quantity)
Manufactured by: (Manufacturer name along with address)

x. **Anticipated cost of the project:** (Details regarding the complete cost of the study as mentioned in the application dossier).

3. Required documents for the application dossier are as under:

S. No.	**Description of Document**	
1	Application on prescribed Form-8 along with an undertaking on affidavit	Provide as attachment

2	Prescribed processing fee challan	Provide as attachment
3	Name of Investigational Product (including all available names; trade, generic or INN name, chemical code, etc.,)	Provide as attachment
4	Dosage Form of Investigational Product	Provide as attachment
5	Formulation of Investigational Product	Provide as attachment
6	Pharmacodynamics and Pharmacokinetics of Investigational Product	Provide as attachment
7	Purpose of study defining the indication along with details regarding anticipated cost of the project and sources of fund	Provide as attachment
8	Investigational design and study plan	Provide as attachment
9	Pre-clinical or clinical data or safety studies	(Brief toxicology summary and list of known adverse events, warnings, and pharmacokinetic summary) Provide as attachment
10	Final protocol along with its summary/synopsis	Protocol Edition/Version No. ……., Dated…… Provide as attachment
11	Provide the evidence of clinical expertise and relevancy of PI/Co-PI, Clinician and analyst with reference of the study.	(CVs of PI, Co-PI's, Clinician and analyst and other research team) Provide as attachment
12	Institutional Review Board (IRB)/Ethics Review Committee (ERC) approval of the trial along with IRB/ERC Notification with complete composition of IRB/ERC committee (as per ICH-GCP and/or DRAP guidelines template for IRB/ERC)	Provide as attachment
13	Approval of the National Bio-ethics Committee (NBC) **or its designated body**	Provide as attachment
15	Informed consent and participant information sheet (In Urdu & English)	ICF Edition/Version No. and Dated:…… Provide as attachment
16	Serious Adverse Event Reporting Form	Provide as attachment
17	Name of the monitor or research associate nominated by the Sponsor (If any)	(Attach CVs of Monitor(s) and research associate along with nomination letter form Sponsor) Provide as attachment
18	Certificate of Analysis of Test Product and GMP Certificate or Drug Manufacturing License of the Manufacturer	Provide as attachment
19	Details regarding reference product (Country of origin, mode of purchase, shipment procedure) along with any other relevant documents if available	Provide as attachment
20	The proposed label of the investigational product (Both test and reference products)	Provide as attachment
22	Details regarding trial participants insurance.	Sponsor and/or PI shall attach insurance details.
23	Name of Sponsor's nominated Contract Research Organization / Service Provider duly approved by DRAP	Please provide the details of assigned tasks, with a copy of the contract and/or letter from the Sponsor (If any), along with details of trial monitors and Clinical Research Associate (CRAs)

UNDERTAKING

I ……. (Principal Investigator of applied BA or BE study titled, "……", hereby undertake / certify that the contents stated above are correct to the best of my knowledge and belief.

Signature

Name of the Principal Investigator
Designation:
Email address:
Contact number:

Date:…….

Form–9

License No: ……

Government of Pakistan
Ministry of National Health Services
Regulation & Coordination
Drug Regulatory Authority of Pakistan

License to act as Bio-equivalence or Bioavailability study center

(Name of Organization) **……**
is/ are hereby licensed to act as center at the premises situated at ……..…….

(2) This license shall be subject to the following and in addition to the conditions as specified under Rule 04 of the Bio-Study Rules, 2017: -

(i) The license shall be valid for the period of three years from the date of issue unless earlier suspended or cancelled.
(ii) The licensee shall maintain the conditions of GCP and GLP.
(iii) Minimum safety standards shall be observed by the licensee.
(iv) The Licensee shall develop SOPs for the conduct of studies and get formal approval from DRAP.
(v) The Licensee shall maintain adequate arrangement for storage of the study material as per protocol of the study.
(vi) The licensee shall ensure that the study material is kept in containers bearing labels indicating the purposes including the security codes for which it has been kept.
(vii) The licensee shall use the investigational product manufactured under the license exclusively for experimental purposes and shall carry out the experimental work at specifically authorized premises.
(viii) The licensee shall allow any member of CSC or any other official nominated by the Chairman CSC to enter, with or without notice, to the premises to satisfy himself that conditions of the license is being met during the study.
(ix) The licensee shall comply with such further requirements, if any as may be specified from time to time either defined under these rules or guidelines duly approved by the Authority.
(x) The licensee shall develop mechanism for disposal of clinical study material or chemical as per defined procedure under rules and ICH guidelines.

Date of issuance/renewal of licence: ……. **Valid Until:** ……..

Secretary CSC
(Signature)

Chairman CSC
(Signature)

Form – 10

License No: ……

Government of Pakistan
Ministry of National Health Services
Regulation & Coordination
Drug Regulatory Authority of Pakistan

License to act as a Contract Research Organization/Service Provider (CRO/SP) or Clinical Trial Site or Bio-analytical laboratory

(Name of Organization) **……** is / are hereby licensed to act as CRO / SP / Clinical Trial Site / Bio-analytical laboratory at the premises situated at ……..

2. This license shall be subject to the following and in addition to the conditions as specified under Rule 04 of the Bio-Study Rules, 2017: -
   (i) The license shall be valid for the period of three years from the date of issue unless earlier suspended or cancelled.
   (ii) The licensee shall maintain the conditions of the latest ICH-GCP and GLP.
   (iii) Minimum safety standards shall be observed by the licensee.
   (iv) License holder shall develop Protocols or SOPs for the conduct of studies or trials and get formal approval from the DRAP.
   (v) License holder shall maintain adequate arrangements for storage of the study material as per the protocol of the study (applicable on CTS only).

Date of issuance/renewal of licence: …….. **Valid Until:** ……..

Secretary CSC
(Signature)

Chairman CSC
(Signature)

Form – 11

Government of Pakistan
Ministry of National Health Services
Regulation & Coordination
Drug Regulatory Authority of Pakistan

License No: ……

License to act as Investigational Products Storage and Management Services (IPSMS)

(Name of Organization) …**……** is hereby licensed to act as Investigational Products Storage and Management Services (IPSMS) at the premises situated at ……

2. This license shall be subject to the following and in addition to the conditions as specified under Rule 04 of the Bio-Study Rules, 2017: -

(i) The license shall be valid for the period of three years from the date of issue unless earlier suspended or cancelled.
(ii) The licensee shall maintain the conditions of GSDP and GCP.
(iii) Minimum safety standards shall be observed by the licensee.
(iv) License holder shall develop separate SOPs for the storage and distribution of IPs and get formal approval from the CSC-DRAP for each contract/order of IPs handling.
(v) License holder shall maintain adequate and separate arrangements for storage of the study material (IPs) as per the protocol of the study supplied by the Sponsor.
(vi) IPSMS shall be responsible for keeping confidential IPs data and formulation.
(vii) This licence doesn't allow the licencee to import IPs without prior approval from CSC-DRAP and the grant of a Drug Import Licence.
(viii) Licencee shall be responsible for the following arrangements/conditions:
  (a) **Temperature-Controlled Storage**
    - Approved range(s): _____
    - The continuous monitoring system must remain active 24/7.
  (c) **Chain of Custody & Documentation**
    - Full audit trail, IPs import and receipt logs, dispatch logs, reconciliation records.
  (d) **Quarantine & Recall Management**
    - Separate designated quarantine space and documented recall SOPs.
  (e) **Security & Restricted Access**
    - Controlled entry, CCTV (90–180 days retention), alarm-monitored facility.
  (f) **Deviation & Excursion Reporting**
    - Mandatory reporting to Sponsor & DRAP for any within specified timelines.
  (g) **Change Notifications**
    - Any change in storage address, temperature systems, QP/QA personnel, or destruction vendor requires **prior regulatory approval**.
(ix) This licence is valid for storage and distribution of investigational products only and does not authorize sale, storage or distribution of medicines under this licence.

Date of issuance/renewal of licence: …….. **Valid Until:** ……..

Secretary CSC
(Signature)

Chairman CSC
(Signature)

Form – 12

Government of Pakistan
Ministry of National Health Services
Regulation & Coordination
Drug Regulatory Authority of Pakistan

Registration No: ……

Registration of Clinical Trial / BA or BE study	
Reference No.:	Dated:
(Name of organization)..... is/are hereby authorized to conduct the clinical trial or study as detailed below at site..... or in such other place as the approving authority may from time to time authorize.	
(1) Title of trial or study:	
(2) Control number:	
(3) Approved protocol version:	
(4) Phase of trial or type of study:	
(5) Purpose of trial or study:	
(6) Investigational products; (a) Chemical name (b) Non-proprietary name (c) Trade name (if any) (d) Manufacturer	
(7) Applicant details; (a) Name (b) Designation	
(8) Principal investigators:	
(a) Name (b) Position (c) Institute (d) Site	(e) CNIC No.
(9) No. of participants to be enrolled:	
(10) Maximum duration of trial or study:	
(11) Further conditions, if any:	
(12) Quantity of IPs and other ancillary items/auxiliary product need to be imported or procured:	

Date of issue: ……..

Secretary CSC
(Signature)

Chairman CSC
(Signature)"

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[File No.13-1/2017 DD (PS)]

(Sheikh Ansar Ahmad)
Director, Pharmacy Services Division
Drug Regulatory Authority of Pakistan, Islamabad