To be published in the extra ordinary Gazette of Pakistan, Part-II

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

Islamabad, the 19th January, 2026.

NOTIFICATION

S.R.O. XXX (I)/2026. — 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 approval of the Federal Government, is pleased to direct that the following further amendments shall be made in the Bio-Study Rules, 2017, namely, —

In the aforesaid Rules, —

(1) In rule 1
(a) in rule 1 sub-rule (2), the word "They", replaced with the word "These";
(b) in rule 1 sub-rule (2), after the expression "Contract Research Organizations,", the expression "/Service Providers (CRO or SP), Investigational Products Storage and Management Services (IPSMS), Bio-Analytical" shall be inserted;
(c) in rule 1 sub-rule (2), after the expression "or organizations", the expression "and healthcare facilities" shall be inserted;
(d) in rule 1 sub-rule (2), after the expression "operating", the expression "as Clinical Trial Site" shall be inserted;

(2) in rule 2, in sub-rule (1), —

(a) after clause (c), the following new clauses (c-i) shall be inserted, namely.—
"(c-i) "Authority" means the Drugs Regulatory Authority of Pakistan established under Section 3 of Drug Regulatory Authority of Pakistan Act, 2012."

(b) after clause (g), the following new clauses (g-i) shall be inserted, namely.—
"(g-i) ""Clinical Research" means any type of Clinical Research (Interventional Clinical Trials or BA/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."

(c) clause (i) shall be substituted with;

"(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."

(d) in clause (j), after the expression "Good Clinical Practice", the expression "or "GCP guidelines"" shall be omitted;

(e) in clause (j), after the word "means", the expression "ICH-" shall be inserted;

(f) in clause (j), after the expression "ICH-Good Clinical Practice Guidelines", the expression "adopted by the Authority." shall be inserted;

(g) in clause (j), after the expression "Good Clinical Practice Guidelines", the expression "or "GCP guidelines"" shall be omitted, and after the expression "means" the expression "ICH-" shall be inserted, and the expression "issued under rule 15, to set a standard for the design, conduct, performance, monitoring, auditing, recording, analyzing and reporting of clinical trials;" shall be substituted with the expression "adopted by the Authority.".

(h) in clause (n), after the expression "medical institution", the expression "or health care facility." shall be inserted, and after the expression "dental facility dully", the expression "licenced or" shall be inserted, and the expression "medical and dental council" shall be substituted with the expression "the relevant Healthcare Commission or Health Regulatory Authority", and after the expression "where clinical trials" the expression "or any of trial related activity or operations" shall be inserted, and after the expression "proposed to be conducted" the expression "after approval from the DRAP" shall be inserted;

(i) after clause (n), the following new clauses (n-i) shall be inserted, namely.

—

"(n-i) "Investigational Products Storage and Management Services" or "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 made there under, 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 trial process."

(j) in clause (o), the expression "provided under rule 9.", shall be substituted with the expression "specified under the latest ICH-GCP Guidelines";

(k) in clause (p), after the expression "investigational therapeutic goods", the expression "or pharmaceutical form of an active ingredient " shall be omitted; and after the expression "an approved use;", the expression "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;" shall be inserted;

(l) clause (q), shall be substituted with following new definition;
"laboratory" means bio-analytical laboratory for activities and services related to clinical trial and BA or BE studies; and

(m) clause (r), shall be rewrite as under:
"Referral Site" 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 IMPs. Details of the referral site(s) need to be mentioned in the protocol for consideration.

(n) after clause (r), the following new clause (r-i) shall be inserted, namely. —
(r-i) "Specialty Clinics" means a healthcare facility dully licenced or registered by the relevant Healthcare Commission or Health 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 studies within its specialty, in accordance with approved protocols, ethical standards, and guidelines approved by the Authority.

(o) after clause (s), the following new clause (t) shall be added inserted, namely. —
"(t) "Therapeutic goods" includes drugs or alternative medicine or medical devices or biologicals or other related products as may be notified by the Authority."

(p) Sub-rule (2), the expression "The terms used but not defined herein shall have the same meanings as one assigned to them by the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) and the Drugs Act, 1976 (XXXI of 1976)" shall be substituted with expression "The words and phrases used but not defined herein shall have the same meanings as are 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) or guidelines duly approved by the Authority.".

(3) In Rule (3)

(a) in Rule (3) heading, the expression "**and issuance of license**" shall be substituted with, the expression "**for grant of licence and fee thereof.**";

(b) in sub-rule (1), the word "purpose" shall be substituted with, the word "grant";

(c) in sub-rule (1), the expression "to act as clinical trial site, BA and BE center or laboratory, as the case may be, shall be submitted on Form-I" shall be substituted with the expression "shall be applied on relevant form specified in the Schedule-A";

(d) in sub-rule (1), the expression "the Chairman or Secretary of CSC," shall be substituted with the expression "the Pharmacy Services Division.";

(e) in sub-rule (2), after the expression "documents, data" the expression "as specified in the guidelines approved by the Authority," shall be inserted;

(f) in sub-rule (2), the expression "specified under the Act. The fee shall be paid in the bank account of DRAP. Incomplete applications shall not be received." shall be substituted with the expression "notified under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules 2022.";

(g) in sub-rule (3), the expression "and scrutinized by the Division of Pharmacy Services" shall be substituted with the expression "as per the guidelines duly approved by the Authority.";

(h) sub-rule (4) and (5) are omitted;

(i) sub-rule (6) is re-numbered as sub-rule (4), in sub-rule (6) after the expression "as specified in the guidelines," the expression "mentioned under rule 4," shall be omitted and after the expression "by the applicant" the expression "/licencee." Shall be inserted";

(j) Sub-rule (7) is re-numbered as sub-rule (5), in sub-rule (7) the expression "Form – IV." Shall be substituted with the expression "relevant form specified in the Schedule-B.";

(k) Sub-rule (8) is re-numbered as sub-rule (6), in sub-rule (8) after the expression "act as CRO" the expression "-SP," shall be inserted, and after the expression "Clinical Trial Site or" the expression "Bio-Analytical" shall be inserted and the expression "Form – V." shall be substituted with the expression "relevant form specified in the Schedule-B.";

(l) The new sub-rule (7) shall be inserted;
"Certificate of license to act as Investigational Products Storage and Management Services (IPSMS), shall be issued on relevant form specified in Schedule-B."

(m) Sub-rule (9) is re-numbered as sub-rule (8), in sub-rule (9) after the expression "decision of the CSC" the expression "and/or the Chairman

CSC" shall be inserted, and the expression "23" shall be substituted with expression "**19**.";

(4) in Rule (4):

(a) Sub-rule (1), the expression "The applicant shall provide premises which shall be suitable for intended use, in size and construction and shall be located in an area free from offensive and obnoxious odours and other possible sources of contamination. The premises must have protective equipment for personnel and emergency firefighting arrangement." shall be substituted with the expression "A licensee shall comply with all the conditions specified in the guidelines approved by the Authority."

(b) Sub-rule (2), (3), (4), (5) and (6) shall be omitted;

(c) Sub-rule (7) shal be re-numbered as sub-rule (2)

(5) in Rule (6): Rule (6), "License holder shall apply for renewal of license three months, before the expiry of the validity period, along with prescribed fee for renewal. A grace period of sixty days shall be permissible along with submission of late fee as specified under the Act, and any such application for the renewal shall not be entertained after expiry of that period. However, applicant can apply for fresh license with full fee if so required." shall be substituted with the expression "The licence holder shall apply for renewal of the licence on the prescribed Form, as specified in Schedule-A, prior to the expiry of its validity period and not earlier than six (6) months before such expiry, together 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."

(6) in Rule (7)

(a) in Rule (7) heading, the expression "**and approval**" shall be substituted with, the expression "**for registration.**";

(b) in sub-rule (1), the expression "approval or" shall be omitted, and after the expression "made on" the expression "relevant" shall be inserted, and after the expression "–II, and Form–II (A), respectively," shall be substituted with the expression "specified in the Schedule-A", and after the expression "the Chairman or Secretary, CSC" shall be substituted with the expression "the Pharmacy Services Division.".

(c) in sub-rule (2), the expression "specified under the Act The fee shall be paid in the bank account of DRAP through challan," shall be substituted with the expression "notified under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules 2022,", and after the expression "along with" the expression "the" shall be inserted, and the expression "Appendix-A and Appendix –B. Incomplete applications shall not be

received." Shall be substituted with the expression "the prescribed forms in Schedule–A.".

(d) in sub-rule (3), after the expression "Division of Pharmacy Services" the expression "for its completeness as per the prerequisites described in relevant Form(s) as per Schedule –A and guidelines approved by the Authority." shall be inserted.

(e) Sub-rules (4), (5), (6), (7), (8), (9) and (10) shall be omitted.

(f) Sub-rule (11) shall be re-numbered as sub-rule (4), in sub-rule (11) the word "approval" shall be substituted with word "registration" and in sub-rule (11) the expression "Form – VI" shall be substituted with expression "relevant form specified in the Schedule-B."

(g) Sub-rule (12) shall be re-numbered as sub-rule (5), in sub-rule (12) after the expression "decision of the CSC" the expression "and/or the Chairman CSC" shall be inserted, and in sub-rule (12) the expression "23" shall be substituted with expression "**19.".**

(7) in Rule (8)

(a) in Rule (8) heading, after the expression "**Conditions for**" the expression "**for registration.**" Shall be inserted.;

(b) In sub-rule (3) after the expression "Quarterly" the expression "progress" Shall be inserted, and the expression "CSC" shall be substituted with the expression "Division.";

(c) In sub-rule (4) the expression "trials or studies" shall be substituted with expression "research", and the expression "Pakistan good clinical practices or" shall be omitted, and after the expression "WHO guidelines" the expression "or the guidelines duly approved by the Authority" shall be inserted.

(d) In sub-rule (5) the expression "adverse reaction" shall be substituted with expression "Serious Adverse Event (SAE) / Suspected Unexpected Serious Adverse Reaction (SUSAR)", and the expression "concerned section of the DRAP." shall be substituted with the expression "Pharmacy Services Division.".

(e) In sub-rule (6) the expression "CSC" shall be substituted with expression "Pharmacy Services Division,", and the expression "investigation" shall be substituted with the expression "clinical".

(f) In sub-rule (7) after the expression "officers of the DRAP" the expression "and/or GCP Inspector," shall be inserted, and the expression "investigation" shall be substituted with the expression "clinical".

(g) In sub-rule (8) the expression "trial or studies" shall be substituted with expression "research,", and the expression "investigation" shall be substituted with the expression "clinical".

(h) In sub-rule (9) the expression the expression “investigation” shall be substituted with the expression “clinical”, and after the expression “different than” the expression “described in” shall be omitted, and after the expression “the” the expression “approved”, and the expression “submitted with the application for approval of the clinical trials or studies.” shall be substituted with expression “and all deviation (which were necessary for wellbeing of trial participants) must be reported to the NBC and DRAP.”.

(i) In sub-rule (10) after the expression “approval from CSC” the expression “and/or the Chairman CSC.” shall be inserted.

(j) In sub-rule (11) the expression “to the investigational study” shall be substituted with expression “of the Clinical Research,”, and the expression “this part as Pakistan GCP or” shall be substituted with the expression “these rules,”, and after the expression “ICH GCP guidelines” the expression “and guidelines duly approved by the Authority.” Shall be inserted.

(k) In sub-rule (12) the expression “investigational study or clinical trials” shall be substituted with expression “Clinical Research.”.

(l) In sub-rule (13) after the expression “The destruction” the expression “and/or export” shall be inserted, and after the expression “The destruction” the expression “of unused” shall be inserted substituted with expression “, expired and/or damaged”, and after the expression “The destruction” the expression “investigational products,” shall be inserted substituted with expression “to the sponsor”, and after the expression “The destruction” the expression “after seeking” the expression “prior” shall be inserted and the expression “CSC” shall be substituted with expression “from the Chairman CSC,”, and the expression “which” shall be substituted with expression “who”, and after the expression “the process of” the expression “Investigational Products (IP) reconciliation and” shall be inserted.

(m) In sub-rule (14) the expression “DRAP” shall be substituted with expression “Director Pharmacy Services Division”.

(n) In sub-rule (15) after the expression “committee or IRB” the expression “and NBC” shall be inserted.

(o) Sub-rule (16) shall be omitted.

(p) Sub-rule (17) shall be re-numbered as sub-rule (16), in sub-rule (17) the expression “trial or study” shall be substituted with expression “Clinical Research” and the expression “CSC” shall be substituted with expression “the Director Pharmacy Services Division.”.

(q) Sub-rule (18) shall be omitted.

(r) Sub-rule (19) shall be re-numbered as sub-rule (17), in sub-rule (19) after the expression "terminate Clinical Trial" the expression "(Phase-I, II and III), and the Chairman CSC may terminate Clinical Trial (Phase-IV) and" shall be inserted, and the expression "approval" shall be substituted with expression "registration,".

(s) in sub-rule (19) clause (a), the expression "Pakistan GCP or" substituted with the expression "the latest", and after the expression "ICH GCP guidelines" the expression "and/or the guidelines approved by the Authority" shall be inserted, and after the expression "required under" the expression "this part" shall be omitted.

(t) in sub-rule (19) clause (b), the expression "Pakistan GCP or" substituted with the expression "the latest", and after the expression "ICH GCP guidelines" the expression "and/or the guidelines approved by the Authority" shall be inserted.

(u) in sub-rule (19) clause (c), the expression "Pakistan GCP or" substituted with the expression "the latest", and after the expression "ICH GCP guidelines" the expression "and/or the guidelines approved by the Authority" shall be inserted.

(v) Sub-rule (20) shall be re-numbered as sub-rule (18), in sub-rule (20) after the expression "by the CSC" the expression "and/or Chairman CSC," shall be inserted.

(w) Sub-rule (19) shall be added;

The Sponsor of a clinical trial may contract out the manufacture of Investigational Medicinal Products (IMPs) to a Drug Manufacturing Licence (DML) holder possessing a valid Good Manufacturing Practice (GMP) certificate issued by the Drugs Regulatory Authority of Pakistan, strictly for the quantities specified in the application dossier and as authorized by the Clinical Studies Committee or the Chairman thereof.

(x) Sub-rule (20) shall be added;

A Clinical Trials and BA or BE Studies registration holder shall comply with all the conditions specified in the guidelines approved by the Authority.

(8) in Rule (9)

(a) In sub-rule (9) the expression "clinical trials or studies" shall be substituted with the expression "Clinical Research,", and after the expression "to seek prior" the expression "or in parallel ethical clearance or" shall be inserted, and after the expression "approval from" the expression "the" shall be inserted, and after the expression "IRB of medical" the expression "teaching" shall be omitted, and after the expression "institutions" the

expression "or health care facility and/or university, where CTS or Center is situated" shall be inserted.

(b) Sub-rules (3), (4) and (5) shall be omitted.

(9) Rule (11)

(a) in Rule (11) heading the expression "**activities**" shall be omitted.

(b) In sub-rule (1) the expression "CSC," shall be substituted with the expression "The DRAP", and after the expression "nominated officials" the expression "and/or GCP Inspectors," shall be inserted, and the expression "random," shall be substituted with the expression "scheduled and/or triggered" and the expression "and monitoring plan of the sponsor" shall be substituted with the expression "and guidelines approved by the Authority.".

(c) Sub-rules (2), (3), (4) and (5) shall be omitted.

(10) Rule (12) shall be omitted.

(10) Rule 13

(a) Rule 13 shall be re-numbered as Rule 12.

(b) In sub-rule (1) the expression "The DRAP, with the approval of Federal Government, shall notify a" shall be substituted with the expression "The", and the expression "consisting" shall be substituted with the expression "(CSC) shall be constituted and shall consist".

(c) In sub-rule (1) clause (b) after the expression "Pharmacy Services, DRAP," the expression "(to be nominated by the Director Pharmacy Services)", shall be inserted.

(d) In sub-rule (1) clause (c) the expression "Chairman, Pakistan Health Research Council or his nominee who may be directly involved in conduct of clinical trials or having experience of conducting clinical trials" shall be substituted with the expression "one expert from NBC (HRI) nominated by the Chief Executive Officer NIH;".

(e) In sub-rule (1) clause (d) the expression "one clinical pharmacist, from a renowned hospital, having at least five years of experience, to be nominated by the Authority;" shall be substituted with the expression "one professor of pharmacology, having a basic degree in medicine, to be nominated by the Authority;".

(f) In sub-rule (1) clause (e) after the expression "of pharmacology" the expression "having basic degree in Pharmacy," shall be inserted.

(g) In sub-rule (1) clause (f) after the expression "bio-pharmaceutics," the expression "at least ten (10)" shall be inserted.

(h) In sub-rule (1) clause (g) the expression "fifteen" shall be substituted with the expression "five (05)".

(i) In sub-rule (1) clause (i) the expression "one representative of Pakistan pharmaceutical manufacturer 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; and" shall be substituted with the expression "One Epidemiologist or Public Health Expert, possessing not less than ten (10) years of relevant professional experience, to be nominated by the Authority."

(j) In sub-rule (1) clause (j) the expression "co-opted member to be nominated by the committee for therapeutic goods or any other specific matter." shall be substituted with the expression "One Clinical Research Expert, having basic degree in medicine, possessing not less than five (05) years of relevant professional experience, to be nominated by the Authority."

(k) Sub-rule (1) new clause (k) shall be added
"One Clinical Research Expert, having basic degree in pharmacy, possessing not less than five (05) years of relevant professional experience, to be nominated by the Authority."

(l) Sub-rule (1) clause (i) shall be re-numbered and shall be read as sub-rule (1) clause (l)
"one representative of Pakistan pharmaceutical manufacturer 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; and"

(m) Sub-rule (1) clause (j) shall be re-numbered and shall be read as sub-rule (1) clause (m)
co-opted member to be nominated by the committee for therapeutic goods or any other specific matter."

(n) In sub rule (2) after the expression "The" the expression "CSC" shall be inserted, and after the expression "ex-officio members," the expression "of the CSC" shall be omitted, and the expression "shall be eligible for" shall be substituted with the expression "shall continue to exercise their power and perform their functions until the nomination of new members and/or the", and after the expression "re-nomination" the expression "of existing member(s) as the case may be," shall be inserted, and after the expression "for one more time," the expression "by the Authority." shall be inserted,

(o) In sub rule (3) the expression "The quorum to constitute a meeting of the CSC shall not be less than five members." Shall be substituted with the expression "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.".

(p) In sub rule (4) after the expression "The CSC" the expression "and the Chairman CSC" shall be inserted.

(q) In sub rule (4) clauses (a), (b) and (c) shall be omitted.

(r) In sub rule (4) clauses (d) shall be re-numbered and read as clause (a), in sub rule (4) clauses (d) the expression "the CSC shall" shall be inserted before the expression "grant, reject or suspend", and the expression "approval" shall be substituted with the expression "registration", and after the expression "of a clinical trial" the expression "s (Phase-I, II and III only). The Director PS shall take decisions (grant, reject or suspend registration) on Phase-IV Clinical Trials" shall be inserted.

(s) In sub rule (4) clauses (e) shall be re-numbered and read as clause (b), in sub rule (4) clauses (e) the expression "the CSC shall" shall be inserted before the expression "grant, reject or suspend a license to", and the expression "center, clinical trial site, CRO and laboratory" shall be substituted with the expression "Clinical Trial Sites, BA or BE studies center, Bio-Analytical Laboratories, Investigational Products Storage and Management Services (IPSMS) and Contract Research Organization (CRO)/Service Provider.".

(t) In sub rule (4) clauses (f) shall be omitted.

(u) In sub rule (4) clauses (g) shall be re-numbered and read as clause (c), in sub rule (4) clauses (g) the expression "renewal or extension of approval or registration to a clinical trial and BA or BE study." shall be substituted with the expression "Director Pharmacy Services Division 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.".

(v) In sub rule (4) clauses (h) shall be re-numbered and read as clause (d), in sub rule (4) clauses (h) the expression "renewal of license to center, clinical trial site, CRO and laboratory." shall be substituted with the expression "CSC shall grant renewal of license(s) under these rules.".

(w) In sub rule (4) clauses (e) shall be added

The Clinical Studies Committee or the Chairman thereof, as the case may be, may grant permission for the manufacture of Investigational Medicinal Products (IMPs) by a Drug Manufacturing Licence (DML) holder possessing a valid Good Manufacturing Practice (GMP) certificate issued by the Drugs Regulatory Authority of Pakistan, provided that such DML holder has a valid manufacturing contract with the sponsor of the clinical trial duly submitted to the Pharmacy Services Division, and subject to prior approval of the clinical trial under these rules.

(x) In sub rule (5) the expression "of its functions" shall be substituted with the expression "special task.".

(y) In sub rule (6) after the expression "The CSC" the expression "and the Chairman CSC" shall be inserted, and after the expression "may co-opt" the expression "any national and/or international" shall be inserted, and after the expression "relevant field for" the expression "review or" shall be inserted.

(z) In sub rule (7) the expression "quarterly" shall be substituted with the expression ", with prior approval from the Chairman CSC", and the expression "written request of its" shall be substituted with the expression "direction of"

(aa) In sub rule (8) the expression "stringent" shall be substituted with the expression "reference", and the expression "and regional or international bodies like WHO, ICH and others" shall be substituted with the expression "for reliance as per guidelines approved by the Authority", and the expression "Provided that" shall be inserted before the expression "any application for", and the expression "approval or" shall be omitted, and after the expression "suspended or put on hold" the expression "by other participating countries of the trial" shall be inserted, and the expression "ICH member countries or stringent" shall be substituted with the expression "reference" and after the expression "shall be rejected" the expression ", suspended or put on hold", and after the expression "process of screening" the expression ", as the case may be" shall be inserted.

(bb) Sub rule (10) shall be added,

"The CSC shall fix the responsibility of offences through a speaking order after examining the case referred to it by the GCP Inspector and/or nominated officers or experts and sanction the prosecution before referring the case to the Drug Courts."

(cc) In sub rule (9) the expression "stringent" shall be substituted with the expression "reference", and the expression "and regional or international bodies like WHO, ICH" shall be substituted with the expression "for reliance as per guidelines approved by the Authority"

(11) Rule 14

(a) Rule 14 shall be re-numbered as Rule 13.

(b) In sub-rule (1) the expression "CRO, clinical trial site, BA and BE center, laboratory" shall be substituted with the expression "Clinical Trial Sites, BA or BE studies center, Bio-Analytical Laboratories, Investigational Products Storage and Management Services (IPSMS) and Contract Research Organization (CRO)/Service Provider", and after the expression

"without prior approval" the expression "of the licence" shall be inserted, and after the expression "from the CSC" the expression "under these rules" shall be inserted.

(c) In sub-rule (2) the expression "permission of" shall be substituted with the expression "approval of the registration by", and the expression "in accordance with the conditions as prescribed under rule 8." shall be substituted with the expression "or the Chairman CSC as the case may be.".

(d) In sub-rule (3) after the expression "permission of the CSC" the expression "or the Chairman CSC as the case may be," shall be inserted, and the expression "may be prescribed" shall be substituted with the expression "specified under the guidelines approved by the Authority.".

(e) In sub-rule (5) the expression "clinical trial or study and BA or BE studies" shall be substituted with the expression "Clinical Research".

(11) Rule 15

(a) Rule 15 shall be re-numbered as Rule 14.

(b) In Rule 15 after the expression "shall adapt the" the expression "latest" shall be inserted, and after the expression "ICH–GCP guidelines and" the expression "relevant ISO-standard (for medical devices trials)" shall be inserted.

(12) Rule 16

(a) Rule 16 shall be re-numbered as Rule 15.

(b) In Rule **16 in heading the expression "approval" shall be substituted with the expression "registration"**

(c) In sub-rule (1) the expression "approval" shall be substituted with the expression "registration", and the expression "conditions of the approval under these rules or violates any of the provisions of the Act or the Drug Act, 1976, (XXXI of 1976) or relevant rules and regulations made thereunder" shall be substituted with the expression "provisions of the Drug Regulatory Authority of Pakistan Act, 2012, the Drug Act, 1976, (XXXI of 1976) rules and guidelines framed there under", and the expression "approval" shall be substituted with the expression "registration"

(d) In sub-rule (2) after the expression "the sponsor" the expression "or its representative or PI" shall be inserted, and the expression "CSC," shall be substituted with the expression "Pharmacy Services Division,", and after the expression "institutional review boards" the expression "and NBC" shall be inserted.

(e) In sub-rule (3) the expression "or approval" shall be omitted.

(f) In sub-rule (4) after the expression "as the CSC" the expression "or its Chairman" shall be inserted, and after the expression "may allow" the expression "and deems fit" shall be inserted.

(g) Sub-rule (5) shall be omitted.

(13) Rule 17

(a) Rule 17 shall be re-numbered as Rule 16.

(b) In Rule 17 the expression "approval" **shall be substituted with the expression "registration"**

(14) Rule 18 shall be omitted.

(15) Rule 19 shall be omitted

(16) Rule 20 shall be re-numbered as Rule 17.

(a) In sub-rule (2) the expression "human subjects" shall be substituted with the expression "therapeutic goods".

(17) Rule 21

(a) Rule 21 shall be re-numbered as Rule 18.

(b) In Rule **21 in heading the expression "Trial" shall be omitted.**

(c) In Rule **21 the expression "**clinical trial**" shall be substituted with the expression "**healthy**", and the expression "**and also to improve both patient safety and preserve data integrity of clinical trials.**" Shall be substituted with "**specifically in Phase-I Clinical Trial and BA or BE Studies, during the IP washout period.**", and the expression "**from the investigator, directly**" Shall be substituted with "**and**", and after the expression "**submitted to the DRAP**" the expression "**Pharmacy Services Division if directed**"

(18) Rule 22 shall be omitted.

(19) Rule 23

(a) Rule 23 shall be re-numbered as Rule 19.

(b) In sub-rule (1) after the expression "decision of the CSC" the expression "or its Chairman" shall be inserted, and the expression "thirty" shall be substituted with the expression "sixty", and the expression "Authority" shall be substituted with the expression "Appellate Board of the Authority"

(c) In sub-rule (1) clause (d) the expression "clinical research organization or center or clinical trial site or laboratory" shall be substituted with the expression "Clinical Trial Sites, BA or BE studies center, Bio-Analytical Laboratories, Investigational Products Storage and Management Services (IPSMS) and Contract Research Organization (CRO)/Service Provider"

(d) In sub-rule (1) clause (e) the expression "CRO or center or clinical trial site or laboratory; or" shall be substituted with the expression "Clinical Trial Sites, BA or BE studies center, Bio-Analytical Laboratories,

Investigational Products Storage and Management Services (IPSMS) and Contract Research Organization (CRO)/Service Provider"

(e) In sub-rule (1) clause (f) shall be omitted.

(f) In sub-rule (2) shall be omitted.

(20) Rule 20 shall be added.

(21) Appendix-A and Appendix-B and its forms shall be substituted with Schedule-A and Schedule-B.

SHAFQAT HUSSAIN DANISH,
Deputy Director (Clinical Research),
Pharmacy Services Division,
Drug Regulatory Authority of Pakistan.

SHOAIB ALI KHAN,
Deputy Director,
Legal Affairs Division,
Drug Regulatory Authority of Pakistan.

The Manager,
Printing Corporation of Pakistan Press,
Islamabad.