MODULE 14 | MEDICAL TRAINING, ACCREDITATION AND RESEARCH

Research Governance, Ethics and Publication Integrity

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LECTURE

Practical hospital governance in Punjab, Pakistan

Protect participants and hospital records.
Approve, monitor and report research properly.

AUTHOR

Dr Qurban Hussain Khan

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SELF-STUDY PDF

Manage research as an institutional responsibility

A useful study needs credible methods, proper permission, protected participants and honest reporting.

- Identify the decisions needed before research starts.
- Check resources, records and participant protection.
- Monitor changes, safety concerns and completion.
- Protect the integrity of results and publications.

OFFICIAL SOURCE

A principle tied to a named law, standard or official guidance.

WORKING METHOD

A practical control or teaching format to adapt to the authorised system.

TEACHING CASE

An invented hospital example, used to practise applying the correct process.

Study output

A research approval file, a study register and a reasoned response to a proposed hospital study.

Module 14 | Presentation 3 of 3. Allow 45-60 minutes with exercises. All explanations are on the pages; check the cited sources before live use.

Know what each source can establish

An ethics principle, a regulatory requirement and a local working method have different authority.

Source	Use in this lecture
Pakistan rules and approvals	Apply the relevant DRAP rules, notified amendments and study-specific conditions to covered research.
NBC-R and institutional review	Identify the appropriate ethics route, scope, decision and continuing requirements.
Academic and publishing standards	Apply HEC and programme policies within their scope; identify WMA and ICMJE as professional standards.
Suggested working methods	Adapt the checklists and registers to the hospital's authorised system. They are not prescribed statutory forms.

HEC = Higher Education Commission; WMA = World Medical Association; ICMJE = International Committee of Medical Journal Editors.

Sources: **R1**: review scope | **R4**: regulatory framework | **R9**: section 7

Research, audit and improvement need a clear route

The label on a project does not settle whether ethics review or another permission is required.

Proposed activity	Useful first question	Administrative response
Research	What question is being investigated, using which people, interventions or records?	Send the protocol through the relevant research and ethics route.
Clinical audit	Is practice being compared with a stated standard?	Use the authorised audit route and confirm any ethics or data decision needed.
Quality improvement	What service change is being tested and what extra risks or data use arise?	Seek the responsible committee's classification before assuming exemption.
Case report or record review	Could a person be identified, and is additional consent or review needed?	Obtain a documented decision; retrospective work is not automatically exempt.

NBC-R provides an exemption application route. The investigator or MS should not simply declare a study exempt.

Sources: **R1**: exemption certificate | **R3**: exemption application

Separate four different permissions

An approval covers the decision and scope stated in that document.

Decision	What it addresses	What to check
Scientific or academic	Methods, supervision and programme requirements.	Relevant scientific body, university or postgraduate programme.
Ethical	Rights, welfare, consent and justified use of data or material.	Responsible ethics committee and any NBC-R requirement.
Institutional	Use of staff, records, premises, money and services.	The officer or body with the power to commit the hospital.
Regulatory	Covered therapeutic-product research and other regulated activities.	Applicable regulator, site status and study authorisation.

A thesis synopsis acceptance, an MS letter and an ethics approval cannot be used interchangeably.

Sources: **R2**: question 1.3 | **R4**: covered research

Check whether NBC-R review is required

NBC-R is the National Bioethics Committee for Research, based at NIH.

The published national scope

- NBC-R identifies research with international research funding, Government of Pakistan funding or support, nationwide or multi-province work, and drug trials for registration for prior national review.
- Read the exact categories against the study. Do not assume every hospital project requires the same national submission.

The local action

- Ask the institutional ethics office to record the route, including local review and national review where required. Resolve unclear cases with NBC-R.
- Keep the decision, protocol version, covered sites, conditions and approval period together. The current digital system also handles amendments and extensions.

NIH = National Institutes of Health. Institutional permission remains necessary for access to the hospital.

Sources: **R1**: projects for ethical review | **R3**: current application types

Protect the independence of ethical review

ERC, REC and IRB are commonly used names for an ethics review committee or institutional review board.

Leadership support

- Provide the committee with time, records, trained support and an approved process for handling applications. Check its constitution, authority and current registration requirements.
- NBC-R publishes an IRB/ERC registration process. Registration of the committee does not approve every study it later receives.

Conflict control

- A committee member who has an interest in a study should declare it and follow the committee's recusal process.
- As MS, request a clear and timely decision through the authorised route. Do not ask the committee to change its conclusion to meet a recruitment or publication deadline.

Keep the administrative review separate from pressure to approve a favoured investigator's study.

Sources: **R3**: IRB/ERC registration | **R6**: paragraph 23

Ask whether the study can answer its question

The ethics file should be supported by an adequate protocol and suitable scientific review.

01 Question

A clear, worthwhile question with a stated knowledge gap.

02 Design

A method that can answer that question without needless burden.

03 Participants

A justified population, selection method and sample size.

04 Measures

Defined outcomes, data fields and collection times.

05 Analysis

A suitable plan prepared with competent methodological support.

06 Feasibility

Staff, time, facilities and funding sufficient for the work.

A large sample cannot repair a biased design. Seek statistical advice before recruitment or extraction of research data.

Sources: **R2**: questions 1.1-1.6

TEACHING CASE

A feasible study needs real staff time

All figures are invented. This example tests workload, not statistical sample size.

Study plan	The team proposes 120 participant visits, each needing 45 minutes of coordinator time.
Direct time	120 x 45 = 5,400 minutes; 5,400 / 60 = 90 hours.
Available time	A coordinator can provide 6 approved study hours each week for 10 weeks: 6 x 10 = 60 hours.
Gap	The direct visit workload alone exceeds the available time by 90 - 60 = 30 hours.
Decision	Reassess the schedule or obtain approved support. Add time for screening, records, calls and queries; ordinary patient care must remain covered.

Do not sign a feasibility statement based only on the investigator's enthusiasm or an expected future appointment.

TEACHING CASE | Illustrative material is identified in the text.

WORKING METHOD

Build one file before authorising hospital access

Use an index so each permission can be traced to the same study and version.

01 Study identity

Title, investigator, sponsor, departments and study version.

02 Methods

Protocol, scientific review and programme requirements.

03 Ethics

Decision letter, consent materials, conditions and expiry.

04 Regulation

Applicable site and study permissions, or recorded scope decision.

05 Resources

Budget, staffing, contracts, safety and support arrangements.

06 Information

Data access, sample handling, reports and closure plan.

Record the competent signatory and any unresolved condition. Permission to discuss a study is not permission to start it.

WORKING METHOD | Illustrative material is identified in the text.

Make consent a real choice

The 2024 Declaration of Helsinki treats voluntary, informed participation as an ethical requirement.

What the person needs

- Use understandable information about the study, burdens, risks, possible benefits and choices. Check understanding; a signature alone does not establish it.
- Explain which activities are research and which are normal care. Refusal or withdrawal must not reduce the standard care available.

How the hospital can check

- Confirm that the current approved information sheet is used in an appropriate language, with a private discussion and a route for questions.
- A useful spot check asks staff to explain how a patient may decline. Review whether recruitment by a treating doctor or supervisor creates pressure.

Use the approved consent process and records. Community or family agreement does not replace a capable adult's own decision.

Sources: **R6**: paragraphs 25-27 and 31

Do not invent an exception to consent

A waiver, alteration or special consent route needs a decision from the responsible review body.

Records and emergencies

- For secondary research using stored data or material, Helsinki requires ethics consideration when obtaining consent is impossible or impracticable.
- For an unconscious patient or a person who cannot consent, use a specifically approved protocol and applicable representative, assent and safeguard arrangements.

MS decision practice

- Require the investigator to show the exact written decision and the conditions it covers. “No contact with patients” is not itself a consent waiver.
- Where the position is unclear, obtain ethics and legal advice before research activity. Clinical emergency treatment and research enrolment are separate decisions.

The MS cannot replace the committee's consent decision with an administrative no-objection letter.

Sources: **R6**: paragraphs 28-32

Check the proposed secondary use

A hospital record or stored sample was collected for a purpose; new research may create new obligations.

Patient information

- Identify who controls access, what fields are needed and whether the proposed use is covered by the consent and ethics decision.
- An approval to study one condition or period should not silently become authority for unrelated data extraction or unrestricted future sharing.

Biological material

- For storage, further testing, transfer or export, check the national biological-material guidance and the approved purpose, consent and permissions.
- Use an authorised material transfer agreement where required. Record the recipient, permitted use, custody, remaining material and final disposal or return.

Removing a name does not automatically make a sample or a dataset impossible to link to a person.

Sources: **R10**: collection, use, storage and export | **R2**: questions 2.3-2.4

WORKING METHOD

Give the study only the access it needs

Agree these controls with the hospital's records, IT and research teams.

01 Minimum fields

Release only the approved data needed for the stated question.

02 Named users

Authorised accounts and a record of who may see each dataset.

03 Coding key

Keep the link to patient identity separately with restricted access.

04 Safe transfer

Use the approved secure route and verify the recipient.

05 Retention

Document the applicable retention period and authorised disposal.

06 Incident route

Name who receives a loss, disclosure or access concern.

Do not send identifiable hospital records to personal email, open links or unapproved online tools.

WORKING METHOD | Illustrative material is identified in the text.

A second site needs its own readiness decision

Shared research should have clear duties before data, participants or samples move.

For each participating site

- List the investigator, recruitment location, ethics route, institutional permission, required regulator decision and local support services.
- Confirm that the relevant approvals actually cover that site and version. Obtain the required amendment when the study adds a site or changes its work.

For the collaboration

- Use a reviewed agreement covering responsibilities, access to data, publication, costs, disputes and the end of the study.
- For international collaboration, check both countries' requirements and required ethics reviews. Obtain specific advice for exports and cross-border transfers.

An overseas sponsor's approval or contract does not automatically authorise activity in a Punjab hospital.

Sources: **R2**: question 1.3 | **R6**: paragraph 23 | **R10**: transfer/export

Check the regulatory route for therapeutic goods

DRAP means the Drug Regulatory Authority of Pakistan.

What requires attention

- Clinical research involving drugs, biologicals or medical devices may fall within the Bio-Study Rules. Use the rules with current notified amendments and the relevant approvals.
- Check the required site status, study authorisation and responsibilities of the sponsor, investigator and other participating organisations.

Before starting

- Use the current DRAP/NBC submission route and check the exact approved protocol, site, product and conditions. Record any question about scope and obtain written clarification.
- A marketed product or a willing sponsor does not establish permission for the proposed research. A pilot study is still subject to the requirements that apply.

The integrated portal coordinates applications; it does not make ethics clearance and regulatory authorisation the same decision.

Sources: **R4**: rules with later amendments | **R5**: DRAP/NBC portal

WORKING METHOD

Check the site before the first trial participant

Adapt this readiness review to the approved study and applicable good clinical practice requirements.

01 Team

Qualified people, assigned duties and protocol training.

02 Product

Receipt, storage, access, dispensing and accountability controls.

03 Facilities

Required laboratory, equipment, records and emergency support.

04 Participants

Screening, approved consent and contact arrangements.

05 Safety

Reporting contacts, escalation and stopping arrangements.

06 Evidence

Current approvals, study documents and a recorded start decision.

An available room and a research coordinator do not establish a functioning clinical research site.

WORKING METHOD | Illustrative material is identified in the text.

Register the trial before enrolment begins

Public registration makes a planned study visible and helps expose selective reporting.

ICMJE publication standard

- ICMJE calls for trial registration at or before the first consent for enrolment. Its trial definition covers assigned health-related interventions, including some service or educational interventions.
- Use an acceptable public registry and a complete record. Ethics approval is not trial registration.

Hospital working method

- Keep the registry identifier, public link and registration date in the study file. Compare its interventions and outcomes with the approved protocol.
- Assign a person to update the record and meet required results-reporting duties. Do not treat late registration as though it happened before recruitment.

WMA also addresses prospective registration. Registry, funder, regulator and journal requirements may have different scopes.

Sources: **R8**: section III.L.1 | **R6**: paragraph 35

Make the financial relationship visible

A research agreement should explain the obligations that the hospital is accepting.

Interests to disclose

- Record sponsor funding, investigator payments, travel, ownership interests and other relevant relationships. Refer conflicts for the required management decision.
- Consider whether recruitment payments or personal relationships could affect eligibility decisions, consent discussions or the reporting of results.

Terms to review

- Obtain authorised finance and legal review of costs, indemnity, insurance where required, treatment or compensation for research harm and continuing obligations.
- Clarify data access, intellectual property and publication rights. Do not accept a clause that leaves the team unable to check or honestly report its results.

A department head should not privately commit public facilities, hospital money or patient data beyond delegated authority.

Sources: **R2**: questions 1.4-1.5 | **R8**: section III.L.2

TEACHING CASE

Price the work before signing the agreement

All values are invented and expressed in PKR. This is a limited cost example.

Participant work	80 participants x 2 study-only tests x 1,500 per test = 240,000.
Other stated costs	Coordinator time 100,000 + data and archiving 40,000 + training 20,000 = 160,000.
Total estimate	240,000 + 160,000 = 400,000. The sponsor offers 320,000.
Gap	400,000 - 320,000 = 80,000 remains unfunded under these assumptions.
Decision	Resolve funding lawfully before commitment. Check omitted costs, taxes, overheads, payment timing and liability; do not shift study-only costs onto patients without authority.

The example excludes any research-injury provision or longer follow-up cost; these require separate assessment.

TEACHING CASE | Illustrative material is identified in the text.

WORKING METHOD

Prepare a study-specific safety reporting plan

The investigator needs a written route that remains usable outside office hours.

1	**Define the events**	Use the applicable definitions for an adverse event, serious event, reaction and other reportable concern.
2	**Identify recipients**	List the sponsor, ethics bodies, regulator and hospital contacts required for this study.
3	**Record deadlines**	Enter the actual reporting clocks, forms and follow-up requirements from current rules, guidance and approvals.
4	**Test escalation**	Confirm who protects the participant, makes the notification, supplies follow-up information and keeps proof of submission.

A routine hospital incident report may be needed as well; it does not automatically meet a trial-reporting duty.

WORKING METHOD | Illustrative material is identified in the text.

Control changes to the approved study

Use one current protocol version and retain the record of what changed and why.

Planned changes

- Route changes to the relevant ethics body and regulator as required before implementation. Assess effects on consent, costs, staffing, records and registry information.
- Examples include a new recruitment site, additional blood sampling, a changed eligibility rule or a different data-sharing recipient.

Urgent protection and errors

- If immediate action is needed to protect a participant, act to protect them and follow the applicable urgent-safety notification process. Do not use this route for convenience.
- Record departures from the approved process, assess their effect and obtain the required decisions. Never rewrite the original record to make an error disappear.

Track required approval and expiry dates; a submitted extension request should not be assumed to grant continued approval.

Sources: **R3**: amendments and extensions | **R4**: applicable study controls

WORKING METHOD

Monitor what actually happens

Choose checks according to study risk and the approved monitoring plan.

01 Recruitment

Eligibility, consent timing and accurate enrolment counts.

02 Documents

Correct protocol and consent versions at the point of use.

03 Data

Source records, missing fields and traceable corrections.

04 Safety

Required notifications, responses and unresolved concerns.

05 Resources

Staff cover, product accountability and budget position.

06 Actions

Finding, responsible person, due date and proof of correction.

External monitoring does not remove the investigator's duties or the hospital's responsibility for its own systems.

WORKING METHOD | Illustrative material is identified in the text.

Close the study without abandoning obligations

Recruitment ending is only one part of closure.

Participants and records

- Confirm any remaining follow-up, care arrangements, results communication and approved post-trial responsibilities.
- Reconcile products, samples, access permissions and essential records. Keep the required archive accessible to the responsible custodian.

Reports and money

- Complete reports to the ethics bodies, regulator, funder and institution where required. Explain early termination and unresolved matters.
- Reconcile receipts, expenditure and liabilities. Set responsibility for publications, registry updates, queries and any later correction of the research record.

Create a closure list with dates and named owners; a departing investigator should hand over the remaining duties.

Sources: **R2**: questions 3.1-3.3 | **R6**: paragraphs 23 and 36

Keep a traceable path from record to result

The research file should show how an authorised dataset became a reported finding.

At collection and analysis

- Preserve the original record. Date and explain corrections, use a defined data dictionary and keep controlled versions of the analysis dataset.
- Record missing data and exclusions honestly. A blank result must not be replaced with an invented value to make a spreadsheet look complete.

At review

- Check a sample of totals against source records. Reconcile participant counts across the protocol, database, analysis and manuscript.
- Keep the method and code or calculation steps needed to reproduce key tables. Restrict access while enabling authorised verification.

Fabrication invents observations; falsification distorts the research record. Neither is a method for resolving a data problem.

WORKING METHOD | Illustrative material is identified in the text.

TEACHING CASE

Use the correct denominator and state uncertainty

All values are invented. The example explains reporting, not clinical effectiveness.

Records	A study enrolled 100 people. Follow-up outcomes are available for 80; 60 of those meet the stated outcome definition.
Observed result	60 / 80 x 100 = 75% among people with recorded follow-up.
Missing outcome	20 / 100 x 100 = 20% of enrolled people have no recorded follow-up outcome.
Incorrect shortcut	Calling 75% the result for all 100 without explaining missing data can mislead the reader.
Decision	Use the pre-specified analysis plan and statistical advice. Report the missingness and limitations; these counts alone do not prove a treatment effect.

A favourable percentage does not justify excluding inconvenient records or changing the original outcome after analysis.

TEACHING CASE | Illustrative material is identified in the text.

Credit contribution and accept accountability

ICMJE uses four criteria together. Seniority or permission to use the hospital is not enough.

Criterion	Plain-language meaning
Substantial contribution	Meaningful work on the question, design, data acquisition, analysis or interpretation.
Intellectual writing or review	Draft the paper or critically review its important intellectual content.
Final approval	Approve the version that will be published.
Accountability	Accept responsibility for resolving concerns about the work's accuracy and integrity.

Give qualifying contributors the chance to complete the other criteria. Agree roles early and confirm them before submission.

Sources: **R7**: section II.A.2

WORKING METHOD

Check the publication before it carries your name

A publication should be supported by an accessible institutional research record.

01 Evidence

Numbers and conclusions checked against the approved study and data.

02 Permissions

Ethics, consent and trial registration described accurately.

03 Contributors

Author contributions, final agreement and appropriate acknowledgments.

04 Transparency

Funding, interests, limitations and relevant prior reports disclosed.

05 Sources

References exist, were read and support the associated claims.

06 Journal

Check publisher identity, peer review, fees and the actual indexing record.

Where academic credit is intended, verify the journal status required by the relevant regulator or university at the applicable date.

WORKING METHOD | Illustrative material is identified in the text.

A similarity report needs expert interpretation

HEC's Anti-Plagiarism Policy, version 2.0, was issued in August 2023.

What to understand

- The policy covers the higher-education and research settings described in its scope. Apply the relevant university and institutional procedures.
- Text matching helps identify material for review. The subject expert must examine attribution and context; a percentage alone is not a complete finding.

How to check work

- Inspect the matched passages, quotation marks, citations and source documents. Also check tables, images and claims that text matching may miss.
- Keep an honest account of the author's contribution. A low overall score is not permission to copy a key result or present another person's ideas as original.

Use the current HEC and institutional criteria for the submission; do not teach one score as a universal safe limit.

Sources: **R9**: sections 4-8; Annexure 3

AI use needs permission, disclosure and checking

The applicable university, programme, employer and journal may restrict or prohibit particular uses.

Publishing responsibility

- ICMJE requires authors to disclose AI assistance appropriately. AI is not an author; people remain responsible for accuracy, originality and attribution.
- Check every reference, number and assertion against real sources. AI output is not a primary research source and must not be used to invent data.

Institutional controls

- Before using an external tool, check whether the proposed use and information transfer are allowed. Keep identifiable records, unpublished confidential data and review material out of unapproved tools.
- Record the permitted assistance and the checks performed. Disclosure does not cure a use that the programme or institution prohibits.

Use the rules for the actual assignment or study. Do not infer that every journal's policy also permits a postgraduate synopsis use.

Sources: **R7**: section V.A; section II.A.4

Respond fairly to a suspected integrity problem

Protect people and evidence while the competent body determines the facts.

1	**Secure the record**	Preserve versions, source data and relevant correspondence with controlled access. Do not destroy, alter or publicly circulate allegations.
2	**Choose the proper route**	Use the relevant institutional, university, regulator or HEC route. Separate plagiarism, data concerns and patient-safety issues.
3	**Use a fair process**	Provide clear allegations, impartial review and the opportunity to respond through the authorised process.
4	**Act on the outcome**	Record the decision, correction route, notifications and any appeal. Use disciplinary powers only through the competent authority.

HEC provides inquiry and appeal procedures within its scope; an MS should not invent a substitute penalty system.

Sources: **R9**: sections 9-11 and 16

WORKING METHOD

Maintain a small institutional research register

A summary register should point to the full file without exposing unnecessary patient details.

Field	What it allows the hospital to check
Study and lead	Unique identifier, title, investigator, department, sponsor and current status.
Approved scope	Protocol version, locations, recruitment target and activity permitted.
Decisions and dates	Ethics, institutional and regulatory decisions; conditions and expiry dates.
Open actions	Safety or data concerns, changes, reports due, responsible person and review date.
Closure and outputs	Final report, archive custodian, publications and outstanding obligations.

Use scheduled reviews to detect expired approvals, unreported changes and studies that have ended without closure.

WORKING METHOD | Illustrative material is identified in the text.

TEACHING CASE

A proposed device study reaches the MS

All people and events in this example are invented.

Proposal	A company asks a hospital to test a new wearable monitor on 60 patients next week.
File provided	The investigator supplies a draft protocol, a foreign ethics letter and an unsigned funding note.
Extra request	The company wants patient names and ECG files sent to its overseas server. It proposes to include the MS as an author.
Pressure	The coordinator says this is only a pilot and can begin while the Pakistan applications are processed.
Your decision	Identify what is missing, who must resolve it and what may occur before recruitment or release of patient data.

The teaching problem concerns governance. It does not assess this fictional device's clinical performance.

TEACHING CASE | Illustrative material is identified in the text.

TEACHING CASE

A reasoned response to the device-study request

Preparatory discussion may continue; no study activity should exceed existing permissions.

1	**Clarify the protocol**	Obtain the final proposal and competent scientific assessment, including the intended data and sample flows.
2	**Confirm the approvals**	Establish the institutional, ethics/NBC-R and DRAP route, including relevant site and study authorisations.
3	**Resolve the commitments**	Review budget, liability, data transfer, consent, staffing and contract terms through authorised officers.
4	**Record the decision**	State the missing conditions and owners. Decline automatic authorship; apply the contribution and accountability criteria.

Do not treat foreign approval, a pilot label, a commercial deadline or an authorship offer as permission to start.

Sources: **R1**: national scope | **R4**: regulatory framework | **R7**: authorship

Apply the correct decision route

Write your answer and the reason before turning to the next page.

1 | Existing records

A resident says a retrospective chart review needs no ethics decision because no new patient visit is planned.

What evidence should the MS request?

2 | Research budget

100 study-only tests cost PKR 2,000 each. Other costs are PKR 50,000. Confirmed support is PKR 210,000.

Calculate the total and the funding gap.

3 | Authorship

An administrator only signs the site permission. The team adds that person as an author to thank them.

Does that role alone meet ICMJE authorship criteria?

The correct answer states both the decision and the reason; it does not rely on a title or a reassuring label.

TEACHING CASE | Illustrative material is identified in the text.

Answers and reasons

Use the evidence, the calculation and the cited source.

1 | Obtain a documented route and decision

Request the protocol, authorised data-access arrangements and the responsible ethics body's approval or exemption decision, including any consent waiver needed. Retrospective design alone does not grant exemption.

2 | Total PKR 250,000; gap PKR 40,000

Tests: 100 x 2,000 = 200,000. Add 50,000 = 250,000. Subtract confirmed support of 210,000: 40,000 remains. Check omitted costs and cash timing before commitment.

3 | No: permission alone is insufficient

Administrative support alone does not meet all four ICMJE criteria. Record the actual contribution and use an appropriate acknowledgment with permission, unless further genuine work meets the authorship standard.

A defensible file records what was approved, what remains unresolved and who can make the next decision.

Sources: **R1**: exemption route | **R7**: sections II.A.2-3

Create a research decision file

Use a non-confidential real case or the invented examples in this lecture.

1 | Study route

Map scientific, ethics, institutional and regulatory decisions for one proposed study.

2 | Readiness record

List resources, data access, consent, safety and open conditions with owners.

3 | Register entry

Set report dates, version control, review dates and the expected closure record.

Peer review: Can another officer identify the permitted activity, supporting evidence and unresolved conditions?

The exercise is a working format. Do not include patient identifiers or confidential sponsor material in a public teaching submission.

WORKING METHOD | Illustrative material is identified in the text.

Sources and continued use | 1

Select a source title or its official-source link to open the document.

R1

NBC-R: projects requiring ethical clearance

Official review scope and exemption route. Check current forms, conditions and directions; no fixed fee or processing-time promise is taught here.

National Bioethics Committee for Research | NIH | **Official source**

R2

Research Ethics: guidance document, 2022

Questions 1.1-1.6, 2.1-2.4 and 3.1-3.3: scientific methods, resources, participants, consent, data, material and reporting.

National Bioethics Committee | NIH | **Official source**

R3

NBC-R digital system and IRB registration notices

Current online routes for review, exemptions, amendments and extensions. IRB/ERC registration is a separate institutional process; check the current policy and status.

National Bioethics Committee for Research | NIH | **Official source** | **IRB registration and current notices**

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Sources and continued use | 2

Select a source title or its official-source link to open the document.

R4

DRAP: Bio-Study Rules, 2017 and amendments

Regulatory framework for covered clinical research. Use the rules with later notified amendments, current directions and the actual study and site conditions.

Drug Regulatory Authority of Pakistan | **Official source** | **2026 amendment notification**

R5

Integrated clinical research and ethics portal

Official DRAP/NBC route for applications concerning clinical research on therapeutic goods. Coordinated submission does not remove separate regulatory and ethical decisions.

Drug Regulatory Authority of Pakistan and NBC | NIH | **Official source**

R6

Declaration of Helsinki, October 2024

International ethical principles; see paragraphs 21-32 on protocol, review, privacy and consent, and 35-36 on registration and reporting. It is not a Punjab statute.

World Medical Association | **Official source**

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Sources and continued use | 3

Select a source title or its official-source link to open the document.

R7

ICMJE: authors, contributors and use of AI

Sections II.A and V.A: four authorship criteria, contributor credit, accountability and AI disclosure. Professional publishing standards; apply institutional restrictions too.

International Committee of Medical Journal Editors | **Official source** | **Use of AI by authors**

R8

ICMJE: clinical trials

Section III.L: prospective trial registration, acceptable registries, author access to supporting data and data-sharing statements. Publication policy is distinct from regulatory approval.

International Committee of Medical Journal Editors | **Official source**

R9

HEC Anti-Plagiarism Policy, version 2.0, August 2023

Sections 4-11 and 16, and Annexure 3: plagiarism, policy scope, institutional responsibilities, inquiry, appeal and interpretation of similarity reports.

Higher Education Commission, Pakistan | **Official source** | **Policy page**

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Sources and continued use | 4

Select a source title or its official-source link to open the document.

R10

National guidelines on human biological materials, 2020

Collection, use, storage and export of human biological materials. Check the applicable consent, ethics, transfer and permission requirements before releasing samples.

National Institute of Health | MoFA | PHRC | **Official source** | **Official guidelines page**

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