Guidelines for Investigators Submitting Research / Audit Protocols to Teaching Hospital, Jaffna for approval

(For Undergraduate, Postgraduate, Medical, and Allied Health Sciences of State Universities))

1. Administrative Requirements

- Project Title – clear, concise, and descriptive.
- Investigators – names, designations, and student registration numbers (if applicable).
- Supervisors – Senior lecturers/Professors of University/ Consultants from Hospitals.
- Departmental Approval – Head of Department (HoD) must endorse the submission before forwarding to Director. If the group of patients are managed by several consultants all relevant consultants should approve.
- Submission Package must include:
    - Protocol (signed by supervisor & HoD)
    - Consent forms / Information sheets (if applicable)
    - Tools (e.g., questionnaire, data collection sheets)
    - ERC approval/ Pending approval / waiver / exemption letter. Undergraduate investigators should have university ethical review committee approval

2. Scientific & Educational Merit

- Clarity of Objectives – measurable and well-defined aims.
- Background & Rationale – adequate literature review, justification of study.
- Methodology – study design, inclusion/exclusion criteria, sampling method.
- Sample Size – justification if applicable.
- Feasibility – completion within stipulated time (undergraduate ≤ 6–12 months, postgraduate ≤ 2–3 years).
- Educational Scope – especially for undergraduate projects, ensure the project is feasible, low-risk, and matches training level.

3. Principles for Conducting Research and Audits at Teaching Hospital Jaffna

1. Patient Care First
    - Research or audits should never compromise patient care or disrupt the smooth workflow of hospital staff.
    - Clinical services and patient well-being must always remain the priority.
2. Confidentiality
    - Strict patient confidentiality must be maintained at all times.
    - Personal identifiers should be removed or anonymised whenever possible.
    - Data access should be restricted only to authorised investigators.
3. Ethical Standards
    - All research and audits must adhere to the highest ethical standards.
    - Prior Ethics Review Committee (ERC) approval or waiver is mandatory before commencing.
    - Written informed consent is required if patients or staff are directly involved.

4. Supervision & Accountability
    - Each research/audit project must have a faculty supervisor responsible for oversight.
    - The Head of Department (HOD) who approved the project shares accountability and must ensure the investigator follows hospital policies and ethical standards.
    - Progress should be periodically reviewed by the supervisor and HOD.

4. Risk & Safety

- Only minimal-risk studies are permitted for undergraduate investigators.
- No interventions outside standard patient care should be done for research purposes.
- Use of experimental drugs/devices requires formal ERC and Ministry approval (not for undergraduate projects).
- Supervisors must take responsibility for ensuring student safety during data collection.

5. Data Handling & Dissemination

- Data must be collected under supervisor oversight.
- Storage must be secure (password-protected files, locked cupboards for paper records).
- Exporting data or samples outside the institution requires written approval.
- Dissemination: results should be presented in dissertations, local symposia, and institutional publications.
- Postgraduate projects may aim for national or international publication, under supervisor

6. Additional Points for Postgraduate & Faculty Protocols

- Can involve higher complexity studies, provided adequate ethics and regulatory approvals.
- Require clear statistical analysis plans and possible collaboration with biostatisticians.
- Expected to contribute new knowledge in addition to training.
- Must specify funding sources and conflict of interest declarations.

Checklist for Administrative Assistant (Pre-Director Review)

1. Administrative

- Project title clearly stated
- Investigators' names & registration numbers provided
- Supervisor details included and eligible
- HoD endorsement/signature present

2. Scientific Content

- Clear objectives and background included
- Study design appropriate for level of investigator
- Timeline feasible (UG ≤ 12 months; PG ≤ 2–3 years)
- Data collection methods described
- Analysis plan mentioned

3. Ethics

- ERC approval letter (or pending) OR waiver/exemption attached
- Consent forms/information sheets provided (if applicable)
- Confidentiality measures described

4. Risk & Feasibility

- Minimal risk only (UG projects)
- No interventions beyond routine care
- Supervisor oversight confirmed

5. Dissemination & Output

- Output plan (dissertation, poster, presentation, publication)
- Data storage and final report submission mentioned

Officer recommendation (tick one):

☐ Approve
☐ Approve after ERC approval
☐ Revise
☐ Reject