Clinical research pathways

Different types of clinical activities and possible pathways for review depending on level of risk. It all starts with the idea for a CLINICAL activity ...

1. CLINICIAN/RESEARCHER/ACADEMIC
   - QUERY ABOUT CLINICAL ACTIVITY

2. CLINICAL RESEARCH MANAGER
3. CLINICAL TRIALS UNIT
4. FMHHS RESEARCH SUPPORT
5. DEPARTMENT OF CLINICAL MEDICINE
6. OTHER SOURCE

Decisions are made based on the nature of the proposed activity:

- If audit, quality assurance, innovation, or case report:
  - DOCUMENT PREPARATION FOR CLINICAL INNOVATION AND AUDIT ASSESSMENT
    - Quality assurance, audit, case report.
    - Review and approval by Clinical Innovation and Audit Committee (CIAC)
    - CIAC FINAL APPROVAL

- If research:
  - DOCUMENT PREPARATION FOR CLINICAL RESEARCH GOVERNANCE ASSESSMENT
    - Feasibility assessment
      - Increasing level of risk
      - Secondary data analysis; clinical research not targeting vulnerable populations.
      - Research project collecting sensitive patient information, clinical trials or dosage modifications.

    - Governance review by Clinical Research Manager/Executive
    - Governance review by Clinical Research Executive
    - Clinical Research Executive and MQ Health Executive review
    - CLINICAL RESEARCH GOVERNANCE ENDORSEMENT
      - Ethics review and approval by Macquarie University HREC
      - Executed research agreements
      - Relevant service approvals
    - MQ HEALTH FINAL GOVERNANCE AUTHORISATION