

Ensuring minimum standards for  
responsible conduct of research in a  
resource poor setting – low cost solutions  
towards research integrity at  
Shaukat Khanum Memorial Cancer  
Hospital and Research Centre  
(SKMCH&RC), Pakistan

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Pakistan

# Pakistan and Egypt had highest rises in research output in 2018

*Global production of scientific papers hit an all-time high this year, estimates show, with emerging economies rising fastest.*

Anita Meheri



Students look at books between shelves in a university library in Cairo

Things are looking up for Egypt's publications. Credit: Barry Iverson/Wamy

Emerging economies showed some of the largest increases in research output in 2018, according to estimates from the publishing-services company Clarivate Analytics. Pakistan and Egypt topped the list in percentage terms, with rises of 21% and 15.9%, respectively.

China's publications rose by about 15%, and India, Brazil, Mexico and

## RELATED ARTICLES

**China declared world's largest producer of scientific articles**

**China becomes world's third-largest producer of research articles**

# Regulatory and Ethical framework

- **Ministry of National Health Services  
Regulations & Coordination Islamabad**



Drug Regulatory Authority of Pakistan

National Bioethics Committee



## The Role of NBC

*NBC is the major, official body to uphold the bioethical principles in all sectors of health-care in the country. The purpose of NBC is to safeguarding the dignity, rights, safety and well-being of subjects who seek assistance to safeguard their health, be their treatment, as the*

Provincial IRBs  
Institutional IRBs



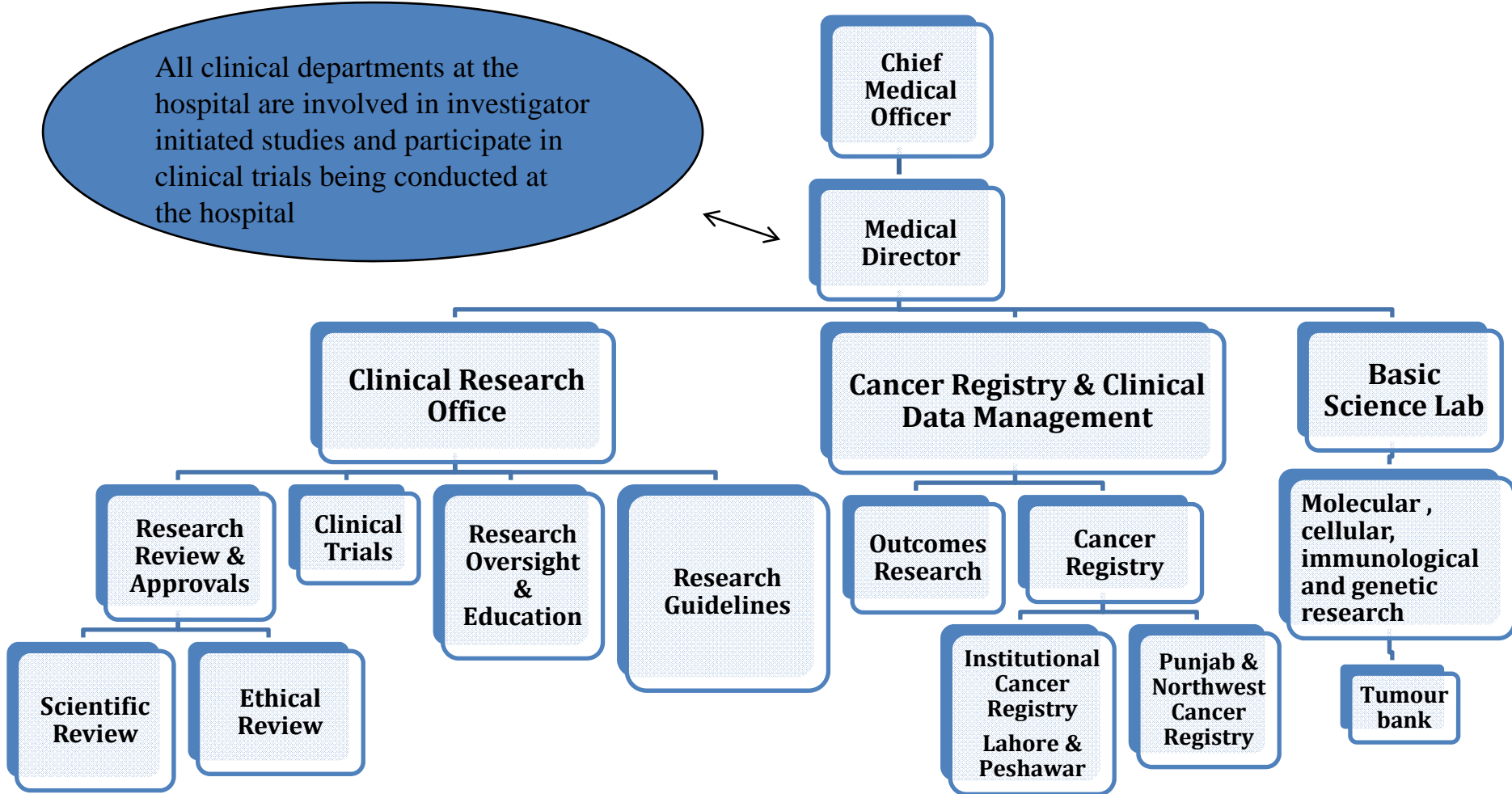
## **Mission**

To act as a model institution to alleviate the suffering of patients with cancer through the application of modern methods of curative and palliative therapy irrespective of their ability to pay, the education of health care professionals and the public and perform research into the causes and treatment of cancer

- SKMCH&RC, a nonprofit cancer treatment and research center
- Runs on charity
- Financially supported patients 75%
- Philanthropic spending to date 421 Million USD

- With minimal external funding SKMC is committed to do research
- Symposium every year, largest oncology meeting in the region, more than 3000 delegated and above 100 guest speakers from all over the world

All clinical departments at the hospital are involved in investigator initiated studies and participate in clinical trials being conducted at the hospital





- SKMCH&RC leadership provides comprehensive research guidance for conducting research since its inception (1994)
- Committed to Ongoing quality improvement
- Motivated for better standards of research practices
- Joint Commission International accreditation

- Compliance remained variable.
- Recognizing emerging threats to research integrity, entire research framework was revised following gap analysis

# Gaps

- Not aware of expected best research practices, code for good research practices
- Misconduct is serious
- Unrealistic expectations for trainees regarding publishing
- Supervision or mentorship of limited quality
- Deviations or failure to follow IRB processes
- Non familiarity with Good documentation practice/record retention requirements
- Unrealistic planning of timelines or missing time allocation for key steps (time needed to secure initial approvals, data collection, recruitment pace)
- No dedicated time, no statistical and methodological support

# Way forward

Institutional responsibility and

Have all players to contribute to research integrity

Research framework, supportive and open communication

# Objectives for reforms

- Entire research framework was reformed as supportive network
- directed to support mechanisms encouraging transparency, full disclosure and honest and *blame-free reporting*
- *Encouraging the researchers to discuss the dilemmas they experience*
- the research leadership also reinforced the legitimacy of these guidelines
- Ongoing Corrective and preventive strategies
- Misconduct prevented fairly....

# Challenges that we faced/institutional challenge

- Limited resources
  - Time for research
  - Training opportunities limited
  - Do we teach basic research methodology, ethics or integrity
  - Funds ???
- Who will train on research integrity
- **Best utilization of what we have**

# Reforms

- Reforms in process
- Reforms in training
- Reforms in mentorship/supervisor role (more meaningful)
- Reforms in Peer review
- Central record monitoring and oversight of ongoing research....major reform
- Reforms in Appraisal

# Reforms in processes

- Detailed guidance (user friendly , more channels of communication, step by step defined processes) – approval process guide with calendar and templates at a central accessible location
- Templates prompting essential information – provide education



# Reforms in training

- Existing Trainings
- General trainings  
(Induction, continuing medical education)
- Individual intensive need based training (for investigators during planning, conduct and reporting phase)

# Reforms in supervision

- Supervisor responsibility for supervision and mentoring reinforced
- clearly defined responsibilities for PI and study team, and supervisor
- accountability across all levels – trainee resident to supervisor
- mandatory documentation of supervisor meeting

# Reforms in peer review

- Robust conflict of interest management
- Timeliness
- More diverse
- Representation from related specialty and basic sciences

# Reforms in appraisal

- **Criteria for assessment of researcher reformed**  
*(Institutional assessment of researchers)*
- Not only the research output to be considered
- Responsible conduct of research for each accomplishment
- Award for responsible conduct of research
- Penalties for misconduct
  - Ongoing CAPA, quality improvement, recognizing the threat and support to deal with it, education
  - **Prevention of misconduct**, early communication
  - Having defined awards/penalties

# Key performance indicators

- Informed consent
- Essential documents

# Central record monitoring and oversight of ongoing research

- Ongoing quality improvement, corrective and preventive actions, recognizing the threat and support to deal with it, education
- **Prevention of misconduct**, early communication
- Having defined awards/penalties
- Transparent and full disclosure by built in processes from protocol to publication

# Impact

- Open and Blame free reporting of problems/threats/dilemmas with timely corrective and preventive actions
- Well known Code of responsible conduct of research
- Total number of active projects 150 per year on average
- All researches benefit from peer review
- Supervisor involvement in all studies
- 2 studies identified with major non-compliance (falsification/fabrication)
- One study from pre-reform time
- One study after reforms
- Minor problems in other studies were identified and were subjected to corrective and preventive actions

# Conclusion

- Minimum resources....minimum standards
- This study evaluates only a small impact within a single institute,
- It shows strengthening research frameworks within institutions, with all the players contributing, can be the first step towards achieving essential minimum standards of good research practices, in a resource poor setting.



- Thanks

