

QUALITÉ

THE PROGRAM WITH A MISSION TO ENSURE AND ENFORCE THE RESPONSIBLE CONDUCT OF RESEARCH MEETING HIGH ETHICAL STANDARDS.



OVERVIEW OF RESEARCH QUALITY MANAGEMENT (RQM)

The Research Quality Assurance (RQA) division was first established under the auspices of the Research & Development Office (RDO). The division worked closely with the Domain Specific Review Board (DSRB) to ensure that research activities across the cluster were carried out in compliance with applicable regulations and guidelines. This initiative was guided by the mission to promote a research culture that adhered to the highest ethical standards within NHG.

In 2011, the Office of Human Research Protection Program (OHRPP) was instituted, and the RQA division was re-designated as the "Research Quality Management" (RQM) unit, the name it still goes by today. RQM's functions are grounded in two broad-reaching and closely intertwined initiatives – Quality Assurance (QA) and Quality Improvement (QI). This article describes the RQM initiatives that have been implemented within its research ambit, with the noble aim of bettering research standards across the NHG community.

QUALITY ASSURANCE (QA) INITIATIVES

Central to the QA initiatives is the conduct of random study reviews of ongoing research studies reviewed and approved by the DSRB. Studies selected for study reviews have their documents and research activities evaluated against institutional and regulatory standards. These standards encompass the Singapore Guideline for Good Clinical Practice (SGGCP), Proper Conduct of Research (PCR) standard operating procedures (SOPs), DSRB SOPs, and applicable legislative requirements for research such as the Medicines (Clinical Trials) Regulations and the Medicines Act.

During the study review, the RQM reviewer corroborates the study staff interviews with documentation in the current study records. Any deficiency in the conduct of the study, suggestions for improvements and/or best practices for study management are then shared with the Principal Investigator and his/her study team. Through this iterative

process, a broad understanding of ground practices and the identification of knowledge gaps are achieved. The RQM team evaluates such study, review data on a regular basis and formulates QA and QI initiatives that seek to address pertinent concerns regarding study conduct. One such initiative was a five-month series of roadshows conducted at nine different institutions in 2012, providing researchers with tips on accelerating their DSRB application process.

Aside from randomly selected study reviews, RQM also conducts "for-cause" study reviews, the purpose of which is to ascertain one or more specific aspects of the study conduct. Such study reviews are typically triggered by requests from DSRB, Research Ethics Committee (REC), Institutional Representatives or complaints from subjects.

The formulation of new research policies and renewal of existing guidelines constitutes an improvement cycle, which forms the second pillar of QA. These include the update of existing PCR SOPs, development of new PCR SOPs, work instructions, guidance documents and templates, and informing the research community on new developments and best practices.

Lastly, RQM also maintains and supports the preparatory activities for the Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation.

QUALITY IMPROVEMENT (QI) INITIATIVES

The second core function of RQM is to develop and implement quality improvement initiatives. The QI initiatives focus on ensuring that the cluster research policies, systems, strategies and resources are relevant, updated and harmonised. The QI team seeks to evaluate quality concerns and provide recommendations for the research community.

Current QI initiatives are classified into two domains – one to address the needs of site staff and another devoted to optimising the DSRB's operational efficiency. The former relies on QA activities to generate study review findings, from which measures are identified in an attempt to reduce future similar occurrences of major and critical findings. The latter explores various means to reduce DSRB review timelines, assist the DSRB secretariat in improving their triaging processes, and identify other areas where the quality of DSRB review may be improved.

CONCLUSION

RQM, through its quality assurance and continuous improvement initiatives, work in synergy with the other OHRPP divisions (DSRB, Researchers Training and Support, Responsible Conduct of Research and Collaboration and Partnership) to achieve human research subject protection. This feeds into its aim of promoting and facilitating ethical conduct of human subject research in NHG and partner institutions.



Team from NHG RQM