INVESTIGATOR'S MANUAL

5th Edition

Research Ethics & Regulatory Requirements For Research Submitted to NHG DSRB

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National Healthcare Group Member Institutions

- Geriatric Education & Research Institute (GERI)
- Institute of Mental Health
- National Skin Centre
- NHG Polyclinics (NHGP)
- NHG Pharmacy
- NHG HQ
- NHG Diagnostics
- NHG Cares
- NHG College
- NHG Eye Institute
- Khoo Teck Puat Hospital (KTPH)
- KTPH@AdMC
- P.H. Feng Research Centre (PHFRC)
- Tan Tock Seng Hospital (TTSH)
- Woodlands Integrated Health Campus
- Yishun Community Hospital YCH)

Partner Institutions

Institutions and organisations with ethics governance under the NHG DSRB

- National University Health System Pte Ltd
  - Alexandra Hospital (AH)
  - Jurong Community Hospital (JCH)
  - Jurong Medical Centre (JMC)
  - National University Hospital (NUH)
  - National University Polyclinics (NUP)
  - National University Primary Healthcare (NUPH)
  - Ng Teng Fong General Hospital (NTFGH)
- Health Promotion Board (HPB)
- Health Sciences Authority (HSA)
- Agency of Integrated Care (AIC)
- Dover Park Hospice
- Ang Mo Kio - Thye Hua Kuan Hospital Ltd (AMKH)
- Lilly Centre for Clinical Pharmacology Pte Ltd

[Effective 1 April 2025] Mutual Recognition of IRB Review for Collaborative Studies

- A*STAR sites or their Partner Institutions
- NHG sites or their Partner Institutions
- NUS sites or their Partner Institutions
- NTU sites or their Partner Institutions
- SingHealth sites or their Partner Institutions

FOREWORD

Clinical research in Singapore has experienced an unprecedented pace of growth, both qualitatively and quantitatively. Our healthcare institutions and research communities have been investing a considerable amount of resources into the search for new knowledge and new solutions for treatment and healthcare delivery. Amidst research growth and evolution through the years, the fundamentals of research ethics have endured and remained relevant. The professional obligation to protect human volunteers and to ensure the scientific integrity and ethical justification of every research study remain the pillars that nurture public trust in biomedical research endeavours. Ethical codes and guidelines such as the Nuremberg Code (1946), the Declaration of Helsinki (1964), the Belmont Report (1979) and the International Council For Harmonisation (ICH) E6 (R2) Good Clinical Practice (GCP) Guideline (2016) are incorporated and referenced by the NHG DSRB in its attempt to uphold high standards of research ethics in NHG and in Singapore.

To ensure that our growing pool of investigators understand ethical research meaningfully, the NHG Office of Human Research Protection Program (OHRPP) published the first edition of the Investigator's Manual in August 2009 as a handy reference tool catering to both new and experienced investigators alike. This publication amalgamates the regulatory requirements, ethical provisions and institutional policies governing research conduct, thereby allowing investigators to adeptly navigate the formidable convolutions of the research maze. Since the launch of the Investigator's Manual, clinical investigators and other members of the research community have given unequivocal affirmation on the utility and value of this publication in providing an essential compass for their research activities.

In tandem with the strong interest in research in Singapore, the local regulations and regulatory requirements have also evolved tremendously. The Medicines Act was first enacted in 1976 but has since seen some of its regulatory controls for clinical trials ported over to the Health Products Act (HPA) (2007), with its regulations for medicines and medical devices. Human biomedical research, an area previously largely overseen by the local institutional review boards in the absence of applicable laws, now has the Human Biomedical Research Act (2015) to look to for regulatory governance. While these new regulations do convert many key ethical guidelines into mandatory standards of conduct and procedures to be met by research institutions and researchers, it is both desirable and conceivable that they will, in the long run, catalyse the development of an ethical research culture and ultimately, a mature environment facilitating exponential advancement in biomedical research.

The fifth edition of the Investigator's Manual provides updated information on the training requirements for investigators conducting clinical research trials regulated by the Health Sciences Authority (HSA), as well as DSRB-supported courses to meet these requirements. With the launch of the new **Ethics and Compliance Online System (ECOS)** platform for ethics review in 2024 (co-

developed by NHG and SingHealth), harmonisation of ethical research provisions and policies at a national level is expected be the next phase in the evolution of research ethics in Singapore.

I hope that investigators and researchers will find this manual both practical and useful, and actively use it to maintain and improve the ethical standards of their research.

Yours faithfully
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