# INVESTIGATOR'S MANUAL

## 4th EDITION

## Research Ethics & Regulatory Requirements For Research Submitted to NHG DSRB

National Healthcare Group

Adding years of healthy life

4th Edition: March 2022


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**National Healthcare Group Member Institutions**

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| ▪ Tan Tock Seng Hospital | ▪ Primary Care Academy |
| ▪ Institute of Mental Health | ▪ Khoo Teck Puat Hospital |
| ▪ National Healthcare Group Polyclinics | ▪ Yishun Community Hospital |
| ▪ National Skin Centre | ▪ Geriatrics Education and Research Institute |
| ▪ NHG College | ▪ Admiralty Medical Centre |
| ▪ NHG Diagnostics | ▪ Woodlands Integrated Health Campus |
| ▪ NHG Pharmacy | |

**Partner Institutions**

Institutions and organisations with ethics governance under the NHG DSRB

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| ▪ National University Health System | ▪ Agency for Integrated Care<br>▪ Ang Mo Kio Thye Hua Kwan Hospital<br>▪ Dover Park Hospice<br>▪ Health Sciences Authority<br>▪ Health Promotion Board<br>▪ Lilly Centre for Clinical Pharmacology<br>▪ Singapore Institute for Clinical Sciences, A*STAR<br>▪ Singapore Institute of Food and Biotechnology Innovation (SIFBI), A*Star<br>▪ Skin Research Institute of Singapore (SRIS), A*Star |
| **IRBs with Mutual Recognition Agreement with DSRB**<br>▪ SingHealth CIRB | **IRBs with Cooperative Agreements with DSRB**<br>▪ NTU IRB<br>▪ NUS IRB |

# FOREWORD

Clinical research in Singapore has been experiencing 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 in treatment and in healthcare delivery. Current trends within NHG's activities in research and innovation reflect a congruent course.

In 2007, the NHG Domain Specific Review Board (DSRB) received only 104 study applications submissions for ethics review. In 2018, this figure stands at 1221 study submissions. The statistics for the number of active NHG Principal Investigators (PIs) are equally encouraging – in 2009, 338 PIs submitted proposals for their research studies. This number has grown to 772 in 2018. Such exponential increases are reflective of NHG's robust research infrastructure to support continued growth in this sector.

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 the biomedical research endeavour. 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 (GCP) Guidelines 2016 are incorporated and referenced by the NHG DSRB in its attempt to uphold a high standard of research ethics in NHG and in Singapore.

To ensure that our growing pool of PIs understand these research ethics 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, allowing PIs 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. Human biomedical research, an area previously largely overseen by the local institutional review boards in the absence of applicable laws, now has the newly minted Human Biomedical Research Act 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.

With the publication of the updated Fourth Edition of the Investigator's Manual, I hope that principal investigators and clinical researchers alike will find this manual both practical and useful, and actively use it to improve the ethical standards of their research.

Yours faithfully

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