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ACCELERATING **RESEARCH**

A NEWSLETTER FOR THE RESEARCH COMMUNITY IN SINGAPORE

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National Healthcare Group
Adding years of healthy life

COLLABORATIVE RESEARCH

EXCLUSIVE INTERVIEW
PROFESSOR STEPHEN SMITH

EVENT HIGHLIGHTS
SHBC 2011 AT A GLANCE

CLINICAL RESEARCH
FEATURE ON CRC & ALLIED HEALTH

SPECIAL FEATURE
KNOWING OUR HEALTHCARE LEADERS
Professor Stephen Smith

contents

from the editor-in-chief

Dear Readers,

Time really flies and we are round the corner to welcome the New Year 2012.

2011 has been an exciting year for NHG Research & Development Office. We put in place many new capabilities and initiatives to support clinical research. We set up a new research ethics board in our Domain Specific Review Board (DSRB) to focus on providing ethical reviews and oversight for community-based research, a new career scheme to nurture clinician scientists and an enhanced support office to coordinate PI-Initiated research studies. We ended the year's activities with the 2nd Singapore Health & Biomedical Congress (SHBC), which received continuous overwhelming support and participation from the Regional Health Clusters.

Moving forward, we will march into 2012 with more aggressive development, and seek to expand our collaborations with NTU and the upcoming Lee Kong Chian School of Medicine (LKCSoM), the third medical school in Singapore. Indeed, we are excited to partner with NTU and LKCSoM, and look forward to achieve tremendous outcomes and breakthroughs in clinical and medical devices research.

I wish to take this opportunity to thank the editorial team for putting in tremendous effort to bring to you the latest updates and news in our local research community through Catalyst, and our Readers for your continuous support and excellent feedback. The editorial team took pride in developing the 4 issues in 2011 and will seek to further expand and improve the content of Catalyst in 2012.

I wish all of you a Merry Christmas and a wonderful new year.

Yours Sincerely,

Kin Poo

Your Newsletter Your Comments

Do you have... Research articles to share? Research topics that you want covered? Comments/Feedbacks on published contents of this newsletter? Comic strips/Cartoon Illustrations that is science /research-related that can bring smiles to your colleagues?

If you have answered "YES" to any of the above, we invite you to write in and share with us your thoughts, feedback on published articles or cartoon clips *(original materials, jpeg format please)*. And if your contribution is accepted for print, we will send you a token of appreciation, with compliments from the Editorial team!

Do remember to add in your contact details, where applicable, for our future communications with you.

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National Healthcare Group
Adding years of healthy life

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PI Feature – SIG Past Awardee Feature

Dr Vernon Lee
Department of Clinical Epidemiology
Tan Tock Seng Hospital

Dengue encompasses a wide spectrum of disease, from benign febrile illness to the more severe forms of hemorrhagic fever and shock syndrome. In Singapore, the two largest dengue outbreaks occurred in 2005 and 2007, underscoring the importance of broadening knowledge of the disease.

Because neither treatment nor a vaccine exists, simple tools to predict disease severity during early illness are crucial to patient management. The NHG Small Innovative Grant (SIG) grant awarded to Dr Vernon Lee at Tan Tock Seng Hospital (TTSH) in 2005 enabled researchers to develop a predictive tool that could accomplish this goal.

Using 1,973 patients from our 2004 dengue cohort, we utilised statistical methods to generate a decision tree algorithm. We found that bleeding history, urea levels >4.0 mmol/liter, and total protein levels ≤67.0 grams/liter identified patients who would develop dengue hemorrhagic fever with a sensitivity and negative predictive value of 100% (overall accuracy 48%).

This simple, effective predictive tool assisted clinicians with deciding whether a dengue patient should be hospitalised or monitored on an outpatient basis. Along with other new clinical admission criteria, the decision tree algorithm was employed beginning March 2007 at TTSH.

A recent retrospective study analysing all dengue patients seen at TTSH from 2006 to 2008 showed a 34.6% mean decrease in hospital admission after the new criteria were implemented.

Those who received outpatient treatment were appropriately triaged and did not suffer any adverse outcome, while those who were hospitalised exhibited more severe signs of dengue, warranting inpatient care. This resulted in a mean cost savings of $2 million (95th percentile savings of $3.7 million) to patients in Singapore in 2008.

In 2008, a five year, $25 million grant was awarded to TTSH by the National Medical Research Council (NMRC) for Scientific exploration, Translational research, Operational evaluation of disease prevention, and Preventative measures through new treatment strategies against dengue (STOP dengue) under Clinical Associate Professor Leo Yee Sin.

This grant has enabled clinicians, laboratory researchers, and government organisations including vector control operations in Singapore to partner together with the common goal of reducing dengue burden locally and worldwide.

Dr Vernon Lee

Clinical Associate Professor Leo Yee Sin
Department of Infectious Diseases
Tan Tock Seng Hospital

"Dengue is a mosquito-borne disease that is endemic to most tropical and subtropical countries. The incidence of dengue has risen rapidly in recent decades due to factors such as urbanisation, travel, and climate change."

PI Research Outcomes – The Singapore Mental Health Study

Mythily Subramaniam, Janhavi Vaingankar, Siow Ann Chong
Research Division
Institute of Mental Health

Mental illness is not only a growing public health concern but also a major social issue that affects individuals and families throughout the world. It has been reported that worldwide there are approximately 450 million individuals worldwide who suffer from some form of neuropsychiatric disorders in their lifetime; community-based surveys have estimated rates of lifetime prevalence of mental disorders among adults ranging from 12.2% to 48.6%.

A landmark study conducted by the World Health Organization (WHO), World Bank and Harvard University, found that of the 10 leading causes of disabilities, four were due to mental disorders.

There have been very few community studies that have specifically examined the mental health of Singaporeans. One of the earliest studies, carried out in 1978 (by the Ministry of Health (MOH)) revealed a prevalence of 8.4% of the population as suffering from "neurosis".

The Singapore Association for Mental Health (1989) estimated that 18% of the population was experiencing Minor Psychiatric Morbidity (MPM). A cross-sectional population survey of over 3000 subjects established a point prevalence of 16.6% with MPM. The National Mental Health Survey 2004 reported lifetime prevalence of depression to be 5.6% of the population and that of anxiety disorders to be 3.4%.

Our study, the Singapore Mental Health Study, which used the latest developments in the field of psychiatric epidemiology, is different from these previous studies in terms of its wider scope and deeper depth. This study was spearheaded by a research team from the Research Division, Institute of Mental health (IMH) along with collaborators from MOH, Nanyang Technological University and Rand Health USA. This 3-year study was funded by the Singapore Millennium Foundation and MOH.

The survey aimed to

(i) establish the prevalence of mental disorders in the adult Singapore resident population including the elderly;

(ii) assess the risk factors associated with the various disorders;

(iii) describe the current use of mental health services (both Western and traditional services) and the level of unmet needs;

(iv) identify barriers to mental health treatment; and

(v) determine the financial, social and personal costs associated with mental illness.

The main instrument used was the Composite International Diagnostic Interview - a fully structured diagnostic instrument, which assesses lifetime and recent prevalence of disorders. We included the diagnostic sections of mood disorders, generalised anxiety disorder, obsessive compulsive disorder, and alcohol use disorders for our study.

Sections on service use, medication use, social network and family burden were also included. Probable pathological or compulsive gambling was established using the South Oaks Gambling Screen while the Fagerstrom Test for Nicotine Dependence was administered for assessing the intensity of physical addiction to nicotine.

The sociodemographic form collected information on age, gender, ethnicity, marital status etc. A checklist of chronic physical conditions was used to collect information on the prevalence of chronic medical illnesses. All the instruments were available in 3 languages - English, Mandarin and Malay.

The survey was conducted from December 2009 to December 2010 following ethical approvals from Institutional Ethics Committees. Each of the randomly selected respondents was notified in advance with a mailed letter to their residence. There was also extensive media coverage to create public awareness on this survey and explain its importance to the local population to encourage participation. The overall response rate for the study was 75.9% (n=6616). The lifetime prevalence of at least one affective, anxiety or alcohol use disorder was 12.0% in the adult population.

The 12-month prevalence was 4.4%. Based on the population census for the year 2007, these prevalence rates mean that overall, approximately 330,200 adults had one of these mental disorders in their lifetime while 121,384 (55,089 men and 66,295 women) of them experienced a mental illness in the past one year. We also found significant association between comorbid physical and mental illnesses.

Our study has provided a rich body of information on the prevalence of mental disorders among the adult resident population in Singapore.

"This data provides important information for policy analysis as well as the basis for future tracking and identification of trends of the mental health status of the local population."

A Tribute to Allied Health Professionals

Ms Doreen Tan

Principal Clinical Pharmacist
Khoo Teck Puat Hospital (KTPH)

Doreen Tan is highly passionate about patient-care work. She has worked over 10 years in a hospital setting where she has initiated numerous clinical services, given numerous talks and written numerous protocols, policies and articles in the fields of Cardiology and Geriatrics.

She believes in running services and research for the sole purpose of improving patient care. She has secured several grants in research over the last 3 years and hope to secure more money in order to further enable the capability in research in Khoo Teck Puat Hospital (KTPH). She is currently undergoing clerkship rotations in the second year of Pharm.D (Doctor of Pharmacy programme, NUS Pharmacy Department).

Her current appointments include adjunct lecturer in the Ngee Ann Polytechnic Diploma of Pharmaceutical Science course, chairperson of the MOH Specialist Accreditation Committee for Cardiology & protem Specialist Accreditation Board Member, writing member of national level practice guidelines and policies like National Pharmacy minimum standards and Clinical Pharmacy services, co-chairperson of KTPH's Antithrombotic Workgroup and Clinical Pharmacy Services IC.

Doreen won the outstanding Pharmaceutical Society of Singapore-Shire award for outstanding hospital pharmacist in 2008. She has also written and won 2 NMRC Enabling Grants and currently holds a NHG-KTPH Small Innovative Grant I. Some of her research studies include: Asian Study of Clopidogrel Pharmacogenomics (ASCLOP), Clopidogrel-Prasugrel switch study in Southeast Asian ACS patients (CLOPRA), Carvedilol-Bisoprolol Therapeutic Exchange and QoL study, Correlation of Oral Anticoagulation Knowledge (OAK) with Time in Therapeutic Range in Warfarin patients, Outcomes of a Pharmacist-managed Inpatient Anticoagulation Consult service among others.

What made you decide to dwell into research pharmacist in this less-known field?

In this era of evidence-based medicine, even though the studies and published reviews are abundant, many address niche populations as defined by their inclusion and exclusion criteria. There are, however, numerous practice-based, daily issues which we do not have enough evidence to support what we do in one way or another.

Furthermore, there is a dearth of good clinical trials which include Southeast Asians in their study populations. Even if there were, these are only miniscule in numbers compared to the preponderance of data in Caucasian subjects. I believe strongly in practice-based research because when we finally look at the health outcomes of our patients, it gives us an idea of how we are doing in the care of our patients.

How do you feel about your research work together with other clinicians and Principal Investigators (PIs) in the hospital environment? Can you share briefly on the research you have conducted and how your support has translated to fruits down the line?

I am grateful that the KTPH (then AH) management, with CEO included, are very pro research in the hospital. I have been very blessed with highly supportive bosses, clinicians and clinical research unit staff who have in large ways enabled the success of the studies at AH/KTPH. Networking has also opened doors for me in looking for collaborators who can complement me with the skills which I do not possess. For example, when we first started up our platelet reactivity studies, it dawned on us that a huge sum of money was required for the start-up.

We needed to buy devices and reagents which we do not already have. I then asked our Finance department for help, and they speedily aided in the procurement of resources using our Endowment Fund. The head of Cardiology, Dr Ong Hean Yee, has always been supportive of what I do whether it was in the capacity of a clinician or a researcher. It is this very reason that his Cardiologists are also supportive of the Cardiology research that we do, going all the way out to support our studies by referring suitable patients.

There have been instances where the consultants call us personally to inform us of suitable patients in their clinic or in the ward! Our Clinical Research Unit (CRU) was pivotal in my journey as a researcher. The director, Associate Professor Lim Su Chi, and his staff in the CRU - Dr Toy Wan Ching (Senior Medical Technologist), Ms Clara Tan (Medical Technologist) and Ms Ng Hooi Ling (Executive) have always offered help to the best of their abilities, whether it was processing and storage of samples, giving their advice or facilitation of any of our studies.

They scrimped at nothing, and are the greatest, most sincere people I have met in any workplace. Special thanks should go to A/Prof Lim for always being impartial in dishing out resources and thinking of us. He even helps in journal watching for us, and forwards us articles related to our research! If not for the help from all these wonderful people, we would not have managed to complete recruitment of our ASCLOP study in that short span of time. Many of the previous smaller scale studies would not have been possible without the help and advice of my previous bosses Ms M K Fatimah and Ms Geraldine Koh either. They have always been my sounding board, and were there for me when I was discouraged with how my studies were going. My current boss, Ms Yong Pei Chean, is highly supportive with respect to resources for my new study, CLOPRA. She has always made sure that the help I asked for is given to me. Special acknowledgements go to my other pharmacy counterparts, who have believed in me and supported me spiritually and in many other ways.

(continue to next page)

Doreen(left) and her colleagues from Khoo Teck Puat Hospital

" The greatest satisfaction I have in my course of work is when I can get it right for my patients. "

Given the high demands of the job, what motivates you to keep going?

I think it is important to keep reminding yourself why you are doing research in the first place. My motivations have always been the singular belief that what we are looking at is for the betterment of our patients. There have been numerous challenges; experiments fail, money runs out, lacking in time because of frontline work. One can choose to focus on all that goes wrong or choose to look forward to the sweet fruits which await you at the end of the long and trying day. It is important to be fully convinced that what you are doing is important, and believe with all your heart that there is no such thing as "cannot do". It helps to have great colleagues who cheer you on too!

What are your daily and greatest challenges faced in your job? What do you enjoy least about your role, and how do you cope with it?

I think the least enjoyable thing about my job is the fact that something will invariably crop up and foil the 100 things I had put on my to-do list. My coping mechanism is to remember that this is why the hospital needs me to be doing what I am doing. If the job's easy, then I wouldn't be needed to fill this role, would I?

What do you enjoy most / find greatest satisfaction about your research work and job?

The research work I do forces me to keep up to date with new studies and research done, including that of newer drugs in the market. With every new drug, it becomes even more confusing for prescribers and other healthcare professionals in the selection of the agents with the correct type of patient population to use them in.

The rising number of medications used in each condition predisposes our patients to an increased risk of adverse effects and drug interactions. The staggering truth is that no patient is simply a renal patient or just a respiratory disease patient; the real-life patient often does not fit the type of patients studied in large published clinical trials. As I have mentioned above, the compounding problem is also that there is very little known about these new agents and their effects on Asian patients.

In the crunching of numerous papers and publications, I have become a stronger clinician. It also makes me a better practitioner when on rounds with doctors. I am more able to promote rational prescribing because I know the evidence and clinical trials well and will be able to select agents based on the patient's medical background and all the other medications he/she is on.

I can do it at the individual level when I see patients in clinic or in the inpatient setting (where I run the inpatient anticoagulation service). But in research, I can do it in a much larger scale when I am able to run studies and share the findings with the medical community. It is my hope that more people are able to do this so that we can promote optimal use of all medications.

How do you handle the tight demands of your schedule?

Marry a supportive husband! I am not entirely kidding with that statement. I have 3 young children, and the oldest is in Primary 3 this year. I think that communication is very important between your spouse and you. If you are not married, make sure you communicate with your parents.

It is great when they see that you are passionate in your work and because of that, they will pitch in to help with family matters. It is also good to have a supportive boss because he/she will be able to give you help with you need it. Most importantly, find an environment with supportive administrators, clinical research unit and clinicians! The moral of the story is, ask for help when you need it.

Was there an interesting / rewarding / memorable incident that you could share with us?

That would be the moment when our ASCLOP preliminary study won us first prize at the KTPH Clinical Research Forum 2011. It was a great encouragement in the blood, sweat and toil which the girls have put in. I am very grateful that I have always had wonderful pharmacists and pre-registration pharmacists who were dedicated to the job and in everything that they did. I would not have come so far without their professionalism and selfless help!

Ms Winnie Chui

Senior Nurse Clinician
Khoo Teck Puat Hospital (KTPH)

What made you decide to dwell into research?

Chronic diseases, unlike acute episodic illness, stay with patients for life, and its progressive and eventual endpoints often contributes to patients' feeling of discouragement, despair and burnout. In caring for people with diabetes, newer discoveries in pharmaceutical agents, treatment delivery alternatives, cells transplantation etc, can become hopeful therapies for people with diabetes to look forward to.

How do you feel about your research work together with other clinicians and Principal Investigators (PIs) in the hospital environment? Can you share briefly on the research you have conducted and how your support has translated to fruits down the line?

In Khoo Teck Puat Hospital (KTPH), I have good research support from the Clinical Research Unit, biostatistician, as well as my clinical head of department, providing me the necessary training, advice and guidance required. One study done on Diabetes Group Patient Education "Using evaluation of participants' knowledge score and clinical outcomes to guide evaluation of program effectiveness", had shown that dynamic interactive group patient education, together with hands-on practical activities could enhance knowledge retention and diabetes self-care capability.

Given the high demands of the job, what motivates you to keep going?

The desire to have patients really benefiting from the various educational programs, seeing improvement in their clinical outcomes of diabetes management, and the encouraging feedbacks received spurs our team on.

What are your daily and greatest challenges faced in your job? What do you enjoy least about your role, and how do you cope with it?

The greatest challenge is the allocation of time among the various activities; patient care, research activities, administrative and staff management. Well, all these roles are essential, and I would have to re-allocate different proportion of energies of the different roles – according to the specific need at that point in time. Of course, I would not compromise the time spent on patient care, as this is my priority as an Advanced Practice Nurse.

What do you enjoy most / find greatest satisfaction about your research work and job?

Besides educational program, other areas of research like looking at aspects of inpatient diabetes management, in-house nurses training, study on patients with microalbuminuria etc have help me with looking at different aspects of things more effectively for both healthcare providers and patients alike. My involvement in clinical nursing has given me great satisfaction.

How do you handle the tight demands of your schedule?

Some of the research activities and administrative planning are done in the quietness of the night, making time in the office for clinical patient care, management issues and the required research consultations.

Was there an interesting / rewarding / memorable incident that you could share with us?

With the support from my organisation, I am glad to have emerged with the Best Poster Presentation Award for the Nursing Category in the 8th Annual Scientific Congress organised by the National Healthcare Group in 2009.

I am also happy that one of my studies on "The Use of Glucometrics in Evaluating the Quality of Inpatient Glyccemic Control" had won access as poster presentation in the Sigma Theta Tau 21st International Nursing Research Congress 2010 in Orlando, giving me the opportunity to travel to the beautiful Florida.

Bibliography: Winnie Chui

2004	Oral presentation on"Benefits of intensive therapy in diabetes management" at Roche Diagnostics Asia Pacific Pte Ltd
2004	Oral presentation on "Transforming diabetes co-management" at Nurses Day Seminar (MOH)
2006	Poster presentation on "To compare the 24 hours ambulatory blood pressure profile in relation to clinic blood pressure in a local population of diabetes subjects with hypertension" in NHG Annual Scientific Congress 2006
2007	Poster presentation on "Ambulatory blood pressure profile: Comparison on clinic blood pressure at target of 130/80 mmHg – A retrospective study" in Disease management conference 2007
2008	Poster presentation on "Impact of patients' self-perception and emotional well-being on knowledge retention and self-care management in NHG 7thAnnual Scientific Congress 2008
2008	Poster presentation on "Inpatient diabetes education program: Evaluation of nurses' knowledge score to guide program development" in Alexandra Hospital Research Forum 2008
2009	Poster presentation on "Diabetes Group Patient Education Program: Using evaluation of participants' knowledge score and clinical outcomes to guide evaluation of program effectiveness" in The 15th Congress of the ASEAN Federation of Endocrine Societies 2009, Bangkok, Thailand
2010	Poster presentation on "The use of Glucometrics in evaluating the quality of inpatient glycemic control" in Sigma Theta Tau 21st International Nursing Research Congress 2010, Orlando, Florida
2010	Poster presentation on "The use of Glucometrics in evaluating the quality of inpatient glycemic control" in Sigma Theta Tau 21st International Nursing Research Congress 2010, Orlando, Florida
2010	Oral presentation on "Risk of raised serum creatinine and potassium levels in patients treated with ACEIs or ARBs among Type 2 diabetes patients with albuminuria and/or hypertension" in KTPH Research Forum 2011
2010	Co-author of a Published article on "Diabetes Management and Hypertension in Safety Sensitive Jobs" in Safe Health Work, 2011:2, 9-16

Institution Feature: Research Division of the Institute of Mental Health (IMH)

The Institute of Mental Health (IMH) is the only tertiary psychiatric institution in Singapore. It is also the first mental health centre in Asia to have received the Joint Commission International (JCI) accreditation. IMH's vision is to do research that will change the way we think about mental illness and/or the way we treat those individuals with mental illness.

With the restructuring of the hospital in year 2000, there was a concerted effort to build the infrastructure and culture for research and today IMH is the leading centre for mental health research in terms of extramural funding, awards (national and international), and publications. The IMH Research Division currently comprises more than 60 full-time research staff.

Another positive development has been the formulation of the first National Mental Health Policy and the subsequent implementation of the Blueprint that also includes an emphasis on mental health research. IMH has undertaken the lead in this agenda including spearheading the Singapore Mental Health Study which was a nationwide study of the mental health status of the resident adult population which was recently concluded. The team concerned has commenced on the planning of an extension study on dementia among the elderly in Singapore. As with the Singapore Mental Health Study, this will be funded by the Ministry of Health (MOH) and the Singapore Millennium Foundation.

We have always operated on 3 principles:

Collaboration: We actively seek out, develop and maintain vibrant and productive partnerships with stakeholders who include persons living with mental illness and their families, advocates, payers, clinical practitioners, researchers, and policy makers.

Communication and Enagement: There should be timely dissemination of actionable relevant research findings to stakeholders including the policy makers, research administrators, patients and the general public.

Focus: In recent years, we have focused on a few key areas selected to optimally leverage on IMH's strengths. IMH has a patient population and service structure that are highly unique across the world. We have accessibility to a large pool of ethnically homogenous patients with limited mobility, detailed medical records, and a high level of clinical expertise. The foci of research – genetics and lipidomics, neuro-cognition, neuroimaging, epidemiology, and health service research - are not mean to be silos but they have been integrated and organized into 2 main programs (see below).

Program for Translational and Clinical Research (TCR)

The aim of this program is to generate scientifically relevant research that will contribute meaningfully to understanding the underlying mechanisms of mental disorder, treatment response, recovery; and/or translating these discoveries into interventions that will relieve the suffering of people with mental disorders. We have established a rich collaborative network with other research centers in Singapore that possess the relevant technological know-how and equipment in building a platform that will enable us to study disease mechanism from the molecular, cellular and system level.

The various foci of expertise within this network includes:

(1) The clinical and neurocognitive characterization of psychiatric symptoms and disorders, and treatment response;
(2) Psychiatric genomics and lipidomics;
(3) Cognitive imaging; and
(4) Interventional studies which includes clinical trials.

The centrepiece of our TCR program is the Flagship Translational Clinical Research programme in Neuroscience. Other active areas of research include a slew of PI initiated clinical trials undertaken by the Department of Child and Adolescent Psychiatry, Department of Early Intervention in Psychosis, and the National Addiction Programme.

Program for Mental Health Policy Research

This program is committed to generate the relevant research findings to stakeholders including the policy makers, research administrators, patients and general public to enable better service development, allocation of resources and patients outcomes. To achieve this, we have made it our modus operandi to seek out policymakers and engage them in order to understand their present and future needs, and the circumstances under which decision makers operate. We have made it a point to work closely with them in these projects to ensure that:

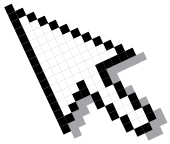
a) Our research meets these needs - both present and future;
b) Be able to discuss possible policy implications of our research; and
c) Help translate our research into practical applications for policy settings.

Through the Singapore Mental Health Study, we have established a focus of expertise in population-based survey research, instrument development and qualitative research. We must ensure that we continue our work in this area through commissioned studies from the MOH and other funders, and to further enhanced our capability to do economic analyses.

The research team within this programme has also taken a number of commissioned studies from various organizations including MOH, Ministry of Community Development, Youth & Sports (MCYS), Ministry of Defence (MINDEF), Ministry of Home Affairs (MHA), and Agency for Integrated Care (AIC).

Useful Websites for Researchers

1. **Tan Tock Seng Hospital Clinical Research Unit**
   www.ttsh.com.sg/clinical-research-unit
2. **Institute of Mental Health Research Division**
   www.imhresearch.com.sg
3. **National Healthcare Group Polyclinics**
   www.nhgp.com.sg
4. **National Healthcare Group Eye Institute**
   www.tei.com.sg
5. **National Skin Centre**
   www.nsc.gov.sg/showpage.asp?id=35
6. **National Healthcare Group Health Services and Outcomes Research**
   www.hsor.nhg.com.sg/Pages/HomePage.aspx
7. **Johns Hopkins Singapore – International Medical Centre**
   www.imc.jhmi.edu
8. **Agency for Science, Technology and Research (A*Star), Singapore**
   www.a-star.edu.sg
9. **Singapore Eye Research Institute**
   www.seri.com.sg
10. **Khoo Teck Puat Hospital Clinical Research Unit**
    www.ktph.com.sg/cru
11. **Nanyang Technological University**
    research.ntu.edu.sg/researchatntu/pages/default.aspx
12. **National University of Singapore**
    www.nus.edu.sg/research/index.php
13. **Singapore Management University**
    www.smu.edu.sg/research/index.asp
14. **NUHS Office of Biomedical Research (OBR)**
    www.nuhresearch.nhg.com.sg
15. **Changi General Hospital**
    www.cgh.com.sg/Medical_Specialities/CTRU/Pages/ctru_intro.aspx
16. **Singapore Health Services**
    research.singhealth.com.sg/Pages/Home.aspx
17. **KKH Research Centre**
    www.kkh.com.sg/research
18. **National Neuroscience Institute**
    www.nni.com.sg/research
19. **National Cancer Centre**
    www.nccs.com.sg/researcher
20. **National Medical Research Council**
    www.nmrc.gov.sg



NHG ROAM – Online DSRB Application Form Guidebook, Version 2

The NHG Domain Specific Review Board (DSRB) has uploaded a new version of the Online DSRB Application Form Guidebook, Version 2. This guidebook will be useful for Investigators and research support teams submitting a research application to the NHG DSRB for approval and serves as a reference and guide to filling up each section of the DSRB online application form.

This updated version includes additional information in the 'Definition / Explanation' section and reflects the updated questions in the DSRB application form compared to the previous version of the B2B Research Online - Online DSRB Application Form Guidebook, Version 1 (2008).

This version also comes with additional clarification or pre-cautionary notes in more prominent areas. For example, under Section B, the clarification of roles for multi-centered studies where NHG and its partner institutions are involved were expanded.

Under Section D - Nature of Research, it was cautioned that data should not be collected prospectively for retrospective data review as this constitutes a major non-compliance. Other than that, it was advised that if a study involves both medical records review and questionnaire, 'questionnaire' should be selected as the 'Type of Research'.

Other new information includes Section E – Study Funding Information where a list of institutions covered under the NHG Clinical Trial (CT) Group insurance Policy was added. The responsibility of sponsors for sponsored studies under the Accelerated Partial Breast Irradiation (APBI) guidelines, the need for additional insurance coverage for non-insured institutions under multi-centered studies and the amount of insurance deductible for every claim were also noted in this guidebook.

The Online DSRB Application Form Guidebook, Version 2 is available for download at the NHG Research Online Administration & Management (ROAM) portal at www.research.nhg.com.sg under the following section:

Resources › Research Online Guidebooks › NHG ROAM – Online DSRB Application Form – Guidebook, Version 2.

Master of Science (MSc) in Clinical Research and Clinical Research Workforce Skills Qualification(WSQ)

Background

Singapore is increasingly seen as a significant hub for Clinical Research in the Asia Pacific region. To help continue this progress, the Workforce Development Agency (WDA) decided to commission the development of an Master of Science (MSc) in Clinical Research/Workforce Skills Qualification in Clinical Research with Edinburgh Napier University.

This course has been specifically designed for Clinical Research Associates (CRAs). CRAs can be involved in all phases of clinical research and at all stages of a particular study. Therefore, possible CRA activities, listed below, include most of the activities required to set up, monitor and complete a clinical study:

- Steering committee organisation and attendance/presentation at meetings
- Protocol and Case Record Form (CRF) development
- Supervision and/or distribution of study supplies, including study drugs
- Co-ordination of Ethics Committee and Regulatory Authority applications and approvals
- Investigator identification and selection
- Co-ordinating investigator meetings
- Pre-study procedures including collation of necessary documentation
- Initiation, monitoring and close-out of study centres
- Archiving of study documentation and correspondence
- Preparation of the final study report

Clinical Research is an international, multi-billion dollar industry. It is highly regulated and increasingly personnel who work in the industry are seeking professional qualifications relevant to their work. The fundamental principles of Clinical Research are enshrined in the Good Clinical Practice Guidelines (2005) and educational developments are largely based around this document.

Edinburgh Napier University

Edinburgh Napier University has a track record of providing innovative programs of under and post graduate qualifications in clinical research to an international audience. The range of programmes offered has been developed in collaboration with prominent healthcare and pharmaceutical partners. Taught by experts in the field, the programmes adhere to the strictest EU/FDA regulations and are externally validated by other UK Higher Educational Institutions, Clinical Research Organisations and the Institute of Clinical Research.

Key Academic Topics In The Course

Clinical Research - Theory

The module includes an exploration of research paradigms and research design; phases of clinical trials; statistics in clinical research; theories and principles of ethics; investigation of ethics in research; exploration of key characteristics of quantitative research and critical appraisal of evidence.

Clinical Research - Legislation and Regulation

The module includes exploration of Good Clinical Practice; International trials legislation; Research Governance; Regulatory Authorities; Ethics Committees/Institutional Review Boards; local approval and inspections/audits.

Clinical Research - Practice

This module will provide students with the knowledge and skills to be able to interpret the practical aspects of the professional roles in clinical research and to apply this knowledge to enhance their ability to improve your practice. The module content includes:

Critical reflection; monitoring and audit of clinical trials; local trial responsibilities; standard operating procedures; ethical and managerial approval; data management; Informed consent; drug accountability; communications skills and exploration of issues related to professional roles in clinical research.

On completion of these modules, students can continue with further study to attain a Masters in Clinical Research by undertaking other modules from the health and biomedical area.

Workforce Skills Qualifications (WSQ)

In addition to the qualification from Edinburgh Napier University, students also undertake a number of competency assessments to attain a WSQ Diploma, Graduate Diploma and Specialist Diploma.

Dr Lynn Kilbride
Director Edinburgh Academy of Clinical Research Education

For more information please contact:

CSM Academy International
250 Sims Avenue, #03-01, SPCS Building, Singapore 387513
Tel: 62962962
Email: csmsupport@csmacademy.edu.sg

Master of Clinical Investigation by the National University of Singapore (NUS)

The Master of Clinical Investigation (MCI) programme has been designed to meet the needs of clinicians in healthcare institutions who desire to incorporate scientifically sound research into their clinical practice.

The programme equips clinicians with the methodological and practical skills to design and conduct clinical investigations relevant to patient care.

These studies will evaluate new treatments and technologies, diagnostic modalities, mechanisms of human disease, determinants of disease outcomes, and effectiveness of health services. The programme also provides the foundation for advanced clinical research training such as a PhD degree. Scholarships are available from the Ministry of Health (supported by the National Research Foundation).

The MCI programme is completed in two years, with the option to extend for a third year if more time is required to complete the research component.

Candidates require 40 modular credits for graduation and must fulfil both coursework and research requirements.

Coursework (32 modular credits)

Nine coursework modules, taught in two six-week blocks of time, form the core requirements for all students.

Topics include:

- Clinical Epidemiology and Biostatistics
- Basic Clinical Pharmacology for Clinical Research
- Molecular Biomarkers for Clinical Research
- Ethics and Regulation of Clinical Research
- Introduction to Health Services Research
- Design, Conduct and Analysis of Clinical Trials
- Scientific Writing

Research Component (8 modular credits)

The aims of the research component are to enable students to apply knowledge, acquire skills to plan a project, and to integrate and sustain research within clinical practice. Students are required to work individually to develop a research project under close supervision. As soon as coursework finishes, students will attend regular meetings and be mentored by a panel of experts to develop their research ideas into fundable research projects. There will also be opportunities to learn other research–related skills such as scientific writing and presentation, and management of research teams.

For more information, please visit www.med.nus.edu.sg/dgms/MCI/index.html

PCR Teasers

NHG's Proper Conduct of Research (PCR) courses are designed to provide Investigators and Clinical Research Coordinators with foundational knowledge of good research practices and to familiarize them with the regulatory requirements and good clinical practice guidelines among others. There are 3 levels to the PCR courses - Basic, Intermediate and Advanced.

Here are a few questions taken from the PCR Basic Courses. Try them!

Question 1: A research study on Diabetes required 100 subjects to be enrolled within one month. Which recruitment method is considered unacceptable?

(a) Provide the database containing patient contact details to a call centre outside the hospital to contact potential subjects.
(b) Publish an advertisement in the newspapers.
(c) Review medical records of subjects visiting the hospital's Diabetes Clinic.
(d) Request for other physicians to refer potential subjects.

Question 2: Which of the following statement(s) is true about advertisements for research studies?

(a) Advertisements for research studies can be displayed prior to IRB review and approval.
(b) Advertisements and any amendments require IRB review and approval.
(c) Advertisements for research studies do not require IRB review and approval.
(d) Amendments to advertisements do not require IRB approval.

Question 3: Which of the following document cannot be provided to a Sponsor?

(a) Subject Screening Log
(b) Subject Identification Log
(c) Subject Enrollment Log
(d) Subject Visit Schedule Log

Did you get them right?

Answers:
1. (a) 2. (b) 3. (b)

Proper Conduct of Research

(For New Investigators, Clinical Research Coordinators or Study Team Members)

Recruiting Subjects

As a recruitment investigative site, researchers together with their team members should first device an appropriate recruitment strategy or plan that will help meet the intended recruitment target and timeline. The recruitment strategy may consist of methods, avenues and operational schedules to which recruiting subjects is possible and most effective. It may be through the Investigator and study team members' own patients, referral from colleagues, other clinics or departments, medical records review or through an existing electronic data standing database. (Note that standing databases planned to be used or are used for research purpose needs to be registered with the NHG DSRB).

If you intend to use a public or direct advertisement, the posters or materials used should meet ethical guidelines and the recruitment method approved in your application to the Domain Specific Review Board (DSRB). You may also need to obtain approval from your respective Corporate Communications departments for advertisements or posters placed in public venues. Items to be submitted include information such as where the material will be used, location of the posters / flyers and the final copy of the advertising material to be used.

The recruitment plan should be based on the specified inclusion and exclusion criteria set in the protocol approved by the DSRB and Health Sciences Authority (HSA) (for clinical trials). The latest approved version of the Patient Information Sheet and Informed Consent Form should also be ready for use. When the study has been explained to the subject in an understandable language, has all questions answered by the Investigator or other medically-qualified staff as appropriate, and given consent to participate, the Investigator may proceed with the screening procedure (if any) or the study procedures or related treatments.

Any subject approached for a study, enrolled, excluded, withdrawn or whom has completed the study needs to be recorded. The Subject Screening and Enrolment Log, documents the chronological screening and enrolment of subjects by assigned screening or trial number. Investigators should also maintain a Patient Identification Log which is a confidential list of names of all subjects allocated to the assigned trial numbers upon enrollment in the trial.

Information to be captured in the Subject Screening & Enrollment log/s include:

- Subject initials and assigned screening or study number.
- The date subject consented
- The date subject was screened
- Whether eligibilty criteria of subject were met (Yes/No)
- The reason for exclusion, if the subject is excluded or not enrolled into the study.

Customizable templates may be found in the NHG Research Portal website (www.research.nhg.com.sg) under the Resources section.

The Role of a Clinical Research Coordinator (CRC)

The Clinical Research Coordinator (CRC) plays an important supporting role to the Investigator in recruiting research subjects. Learn more about Subject Recruitment from experienced research coordinator / managers in the Proper Conduct of Research – Basic II (PC102) module!

The NHG's Proper Conduct of Research (PCR) training courses aim to ensure that Clinical Research Team Members are able to understand the key principles of Proper Conduct of Research SOPs and apply their knowledge in their work.

For more information or to register for the online Proper Conduct of Research (PCR) course, go to: *www.research.nhg.com.sg* (Training and Education › Search for a Course › PCR Online)

References:

- NHG Investigator Manual (Section 8.2)
- NHG PCR Standard Operating Procedures 501-C02 Subject Recruitment and Screening
- Singapore Guideline for Good Clinical Practice (SG-GCP)
- *www.research.nhg.com.sg* (Resources › Research SOPs)

Responsible Conduct of Research (RCR)

The RCR division in NHG Office of Human Research Protection Programme (OHRPP) is in the process of developing a set of research best practices to address tricky issues, in areas such as Research Misconduct, Protection of Human Subjects, Conflicts of Interest, Data Management Practices, Mentor and Trainee Responsibilities, Collaborative Research, Authorship and Publication, and Peer Review.

As there are 8 different components to RCR, the overview of Research Misconduct will "kick off" the RCR components series.

It is believed that the occurrence of misconduct is a threat to the basic principles of research and damages the integrity of the profession and undermines the credibility of the research community.

The research misconduct is defined as fabrication, falsification, plagiarism in proposing, performing or reviewing research, or in reporting research results. Research Misconduct however does not include honest error or differences of opinion. The following defines what research misconduct is.

Fabrication: Refers to the deliberate act of making up of data or results and recording them.

Falsification: Refers to the manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism: Refers to the appropriation of another person's ideas, processes, results or words without giving the appropriate credit.

Stay tuned for more information on the rest of the RCR components in upcoming issues of Catalyst.

Post-Approval DSRB Monitoring – Study Status Report

Continuing Review is a monitoring mechanism to ensure that continuing safeguards are in place to protect the rights and welfare of subjects. It also allows the DSRB to determine whether the study's risk/benefit ratio has changed with its progress.

The DSRB conducts continuing review of ongoing research (except studies that fall under Exempt review category) at intervals appropriate to the degree of risk, at least once per year.

Timely Submission of the SRF

The Principal Investigator should submit a completed Study Status Report Form (SRF) via DSRB's ROAM portal, at least 4-6 weeks before study expiry (as indicated in the approval letter of the study). When a study has expired, all research activities, including recruitment, advertising, screening, enrollment, interventions and interactions, and collection of identifiable data must stop. Therefore, keep abreast of your study approval periods and look out for the reminder emails that are sent at least a month before study expiry!

Section A: Study Status

It is important to select the most relevant study status as this also determines the mode of renewal review. For example, a Full Board study that has yet to be initiated will undergo expedited study renewal (if no additional risks have been identified).

For the study status – *Ongoing (Enrollment closed, Participants on follow up only), do ensure that all subjects have completed research-related activities and that the research remains active only for long-term follow-up of subjects.*

Section B: Subject Recruitment Information

In this section, provide the breakdown of subjects recruited according to the number screened, enrolled, completed, withdrawn and by gender. Do ensure that the figures add up! For retrospective review studies, the 'number of subjects enrolled' can be taken to be the number of records reviewed.

As subject recruitment is an important gauge of the progress of a study, it would be helpful to state the reasons for slow/no recruitment in the past year as this would facilitate renewal review.

Section C: Description of Subjects Enrolled

This section exists to ensure that there are appropriate safeguards for vulnerable populations and that informed consent is properly carried out. While it is common for non-English speaking subjects to be recruited, it is also of utmost importance that these subjects are consented in a language that they understand. Therefore, DSRB requires your declaration of the means of consenting these subjects (e.g. using a translated consent form and/or in the presence of an interpreter etc.).

Section D: Report of Research to Date

In this section, do share information about the progress of the study, such as information about recruitment challenges, participant experience while on the study, and any other information related to the overall execution of the study. It is also a good time to check that the correct versions of documents are being used on-site and also to ensure that proper confidentiality measures are still in place to protect research data. The SRF is also a good platform to share with DSRB any interim findings, analyses or Data Safety Monitoring Board (DSMB) reports. All these will shed light on study progress and facilitate renewal review.

A SRF should be submitted even if the study has been completed/suspended/terminated.

Do not miss Continuing Review!

Knowing Our Healthcare Leaders

Interview

Prof Stephen Smith
Founding Dean
Lee Kong Chian School of Medicine

Vice-President(Research)
Nanyang Technological University(NTU)

1. **Under your leadership, the "(Imperial College Healthcare) NHS Trust successfully bid to become a comprehensive biomedical research centre, the largest in the UK"** *(www.imperial.nhs.uk/aboutus/news ‹www.imperial.nhs.uk/aboutus/news›)*. **As founding Dean of the Lee Kong Chian School of Medicine, how do you hope to translate that experience into building a comparable centre in Singapore?**

   There is an old-fashioned view that the teaching of medicine involves the accumulation of huge amounts of facts so that every doctor can and will become a thoughtful, caring and clever doctor, always right in her diagnosis and where all operations go without complications. The body of knowledge learnt so early in one's career will last for a life time. Unfortunately this is not the case. Lifelong learning, working in multi-professional groups, empowering patients and most of all, everyone being an innovator in health is the only way forward. To achieve this we need to move from the rigid professional structures and thinking that have epitomised medicine in the late 20th century. Twenty first medicines will be totally different and this more radicalised approach needs an "academic" environment in which reflection and innovation plays a substantially larger part than hitherto. This is best achieved in an environment of enquiry and learning and that is what we seek to achieve in the new school with our healthcare partners.

2. **Do you foresee any challenges or similarities between the formation of the first academic health science centre (AHSC) in UK versus the joint venture between Imperial College London and NTU to establish the Lee Kong Chian School of Medicine (LKCSoM)?**

   There are many challenges to our new endeavour but my experience so far has been very encouraging. Most particularly the commitment and desire to deliver better healthcare in the NHG by focusing on education and learning is a very strong part of the ethos and this provides a rich ground for building the new type of medicine that will be practiced in the future.

3. **You led and "championed the integration of research, teaching and healthcare at Imperial – not just in Medicine but right across our Engineering and Natural Sciences faculties and the Business School" (Sir Keith O'Nions, Rector, Imperial College). How did you manage to influence and pull these different disciplines to create this unique culture in the system?**

   One of the greatest challenges in bringing a university to the healthcare sector is not strangely the reticence of the healthcare partner but the disruption that this complex relationship brings to the quieter and perhaps more tranquil world of academe. This is a substantial challenge.

4. **Can you share with us about your thoughts on critical factors that would help determine the success of this joint venture between Imperial and the NTU?**

   The coming together of two world-class universities to jointly establish the Lee Kong Chian School of Medicine is momentous partnership. There are various measures of success for this joint venture. We would have succeeded tremendously when LKCSoM makes it mark on the world stage as a premier medical institution known for its world-class education and innovative research. When we succeed, Imperial and NTU succeed. To succeed on this grand scale would depend on various factors at many levels, the most important of which is people, people and people. We need to

Interview

bring the two groups of people coming from two institutions with different cultural and scientific lineage into a single vision, i.e. the LKCSoM vision of producing doctors of tomorrow. We need a world-class faculty, the clinician-scientists and clinician- educators to develop new systems-based approach to the New Medicine of the 21st century and train the doctors of tomorrow. We are also blessed to have a very experienced Pro-Tem Governing Board to guide and embed the School into the Singapore landscape as the country's new medical school. Of course, the funding from Ministry of Education (MOE) is the practical and all-important ingredient in the recipe of success.

5. What is the kind of impact and influence on Singapore Healthcare that you hope to realize in the development of the LKCSoM?

With LKCSoM focus on stratified medicine, the school hope to develop and lead translational research with the aim of bringing about better patient outcome at lower costs to Singapore healthcare. The school will leverage on its rich engineering expertise at NTU to deliver healthcare solutions in a faster, cheaper and better fashion. Ultimately, LKCSoM hope to help move the Singaporean healthcare from its one-size fits all model to the direction of the New medicine whereby individual patients receives personalized and more effective healthcare treatment.

6. What would you identify as the key performance indicators that the new LKCSoM has achieved what and where you want it to be? Is there an endpoint that you envision it to be?

In practical terms, we would have arrived when we are able to attract medical students to LKCSoM, who would otherwise have applied and gone to Stanford, Oxford or other top medical schools in the world. The School also envisions itself to be a premier research destination for postdoctoral training in clinical and translational medicine where emphasis will be placed on the quality of research conducted. These are lofty ambitions and we hope to get there eventually.

7. How will the integrated medical and research education promote and lead to the development of Key Opinion Leaders in research in Singapore?

Leadership in research is about understanding the science well enough but being able to see and understand the position and views of other colleagues in other branches of science. Medical schools provide a rich environment for these interactions. Much effort and time is needed however to ensure that all parties see the value that each other brings to the enterprise and most importantly, all parties must value and hold in high esteem their collaborators as equals.

8. There is an increasing appreciation of the need to translate research findings into clinical applications. If you have only a million dollars and you have to implement a measure to motivate this, what would you do?

Absolutely. It is only through translation of research into clinical applications that the public will appreciate and realize the importance of research and the research investments necessary to secure the Singapore of tomorrow. If I have only a million dollars, I would offer it as a seed grant to enterprising scientists having a brilliant idea, investing in the idea to turn it into a company. Alongside, I would offer create an environment for the start-up to tap upon the experience and wealth of industry veterans and tech angels. The aim is to build a Singaporean brand name and clinical healthcare product at the end of the day.

9. With so much on your hands, how do you find a work-life balance?

Having been a gynaecologist in my earlier life timing and putting aside sets of time was never an option as childbirth is notoriously unpredictable. That requires from a very early phase of one's professional life the need to organise in the context of a chaotic environment!

10. Do you have any hobbies? And how does your personality and love for your hobbies help in making decisions in your daily work?

I used to have time to fly aeroplanes which is a totally engrossing experience. I do not have the time now so at least I can imagine flying. I like socialising so an easy hobby to achieve.

11. How are you finding Singapore and what would you miss about the UK?

I and my partner are really enjoying our time in Singapore. We like the vibrancy and ever active nature of the place and the people. Being in Asia at this time is very exciting. We certainly do not miss the cold about the UK and honestly are not in any way home sick. The British have a rather long history of setting off in boats and setting up elsewhere, maybe it's in our blood.

ROAM – Top 10 Frequently Asked Questions

Yeo Kian Wah, CIP
Research & Development Office
NHG

1. What does "Domain" on the login page refer to?

If you are a Staff member of NHG Institutions or NUHS, you should be using your Active Directory account (ADID) to login to the ROAM portal, hence your Domain value should be selected as "*NHG*". Otherwise, external non-staff users who are logging to the ROAM portal should chose "*Not Applicable*".

2. I have forgotten the password to my Active Directory account (ADID), can I use the "Forget Password" function on the login page?

No, the "Forget Password" function is only for users who are **NOT USING** the Active Directory account to login to ROAM. If you have forgotten your Active Directory account login, please contact the ITD Helpdesk (1800-483-4357) for assistance.

3. Why do I get duplicate email notifications from the ROAM system?

This is likely due to the duplicate email addresses that you have set in your ROAM account profile. Under the "Profile", "Contact Info", you will find the settings for the email addresses under "Account email address" and "Correspondence email". The ROAM system will send any notifications to both the addresses listed here, even though they are the same email addresses.

4. I am trying to create a new ROAM Account, but I am getting an error message that says, "*An account with the NRIC/FIN already exists in the system. Please login your existing account.*" What does this mean?

The ROAM system only allows each person to have 1 account based on their NRIC/FIN. If you see this message, it is likely that there is an existing account with the same NRIC/FIN.

You will not be able to create any more new accounts. Please contact the ROAM Helpline (6496 6979/researchonline@nhg.com.sg) for assistance.

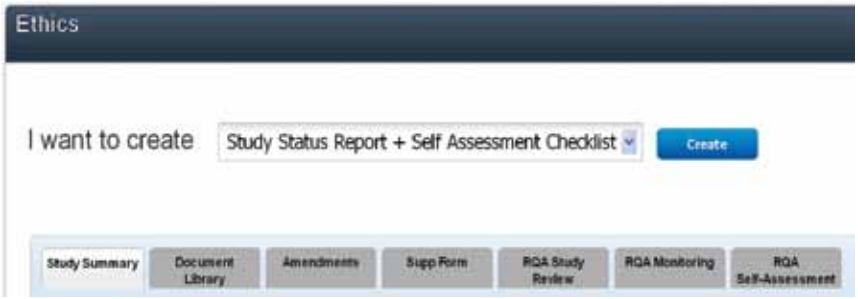
5. I have previously notified DSRB of my minimum training status completion. Why does ROAM still reflect my status as "*Not completed*".

The checking and updating of the minimum training status for users is a manual process as we do not have any data links with the CITI Training site or the Basic GCP course providers.

The minimum training status will not affect the submission or review process by the DSRB. If the DSRB does not have any records of your minimum training status, this will be reflected to you as a review query. You may also contact the DSRB (6471 3266) to confirm your minimum training status.

6. I need to extend/renew the ethics approval for my study. How do I go about doing this?

First, you will need to locate your study in your ROAM account. Once you see the Study summary page, you will see a droplist of Forms which you can create. For renewal of DSRB Ethics approval, you will need to submit the "Study Status Report + Self Assessment Checklist" form to the DSRB at least 6 weeks BEFORE the expiry date of the ethics approval.



7. I am trying to create a new 'Study Status Report + Self Assessment Checklist' or Study Amendment Form but the system keeps telling me that "....*There is already an Amendment/Status report form(2xxx/123456-AMDxxxx) in process for this study...*" What does this mean?

For the 'Study Status Report + Self Assessment Checklist' and Study Amendment Forms, the ROAM system will only allow 1 instance of each form to be created and review at any one time.

Users will not be able to create another form until the previous Form has been either approved or rejected by the DSRB.

Example: If there is an existing draft form of a Study Amendment form, or there is a Study Amendment still being reviewed by the DSRB, you will not be able to create another new draft Study Amendment Form.

To see any Amendment Forms, click on the "Amendments" tab. For Status report forms, click on the "Supp Form" tab.

8. I've just submitted my application form to the DSRB but I've forgotten to include some information/attachment, can I recall my application and make changes?

No, once your application form has been submitted, no further changes are allowed.

However, you can contact the DSRB to inform them that you need to submit additional information. The DSRB will likely allow these changes to be made during the query phase of the review process. Please contact the DSRB (6471 3266) for more information and assistance.

9. Where can I find a reference list of questions for the DSRB Application Form?

We have a comprehensive guide to all the possible questions that you may come across in the DSRB Application Form. The Guide is available for downloading here (*www.research.nhg.com.sg* -› Resources -› Research Online Guidebooks -› "*NHG ROAM - Online DSRB Application Form - Guidebook, Version 2*")

We urge all investigators to use this Guide to prepare their submissions offline before attempting to submit their applications in the ROAM system

10. Where can I find more information about how the ROAM system works?

We have a general ROAM user guidebook which is available for downloading here (*www.research.nhg.com.sg* -› Resources -› Research Online Guidebooks -› "NHG ROAM - Researchers' Guidebook, Version 1").

There are also several other guides available which would be very helpful for users.

- NHG ROAM - How to complete Section B (Overall PI & Study Team) of the online DSRB Application Form, Version 1
- NHG ROAM - Guidebook for Creating External User Account (non-NHG)
- NHG Investigators' Manual - All that an Investigator Needs to Know (PDF), 1st Edition, August 2009

Upcoming Grant Calls in Singapore

1. A*STAR - 3rd Biomedical Engineering Programme (BEP) Grant Call

The BEP seeks to foster Clinician-Engineer collaborations to develop medical devices and solutions to clinical problems. In particular, it supports collaborative research projects with emphasis on devices, procedures, diagnosis, and clinical systems to improve patient care and cost-efficiency of the healthcare system.

Eligibility
Each proposal must involve collaboration between a Clinical lead-PI and a Technical lead-PI. It is also mandatory that a Science and Engineering Research Council (SERC) researcher is present in each research team applying for this grant.

Funding
Interested applicants may apply for either one of the two grants under BEP, namely Proof-of-Concept (POC) or Proof-of-Value (POV). A POC application is for ideas that do not have an existing prototype or device for a particular clinical need and the funding quantum is from S$250,000 to S$500,000.

The POV application is for projects that have an existing prototype or device that has been previously developed from funding from other grants for a particular clinical need. The funding quantum is from S$1million to S$1.5million.

Submission & Deadline Details
The deadline for the softcopy submission of Pre-Proposal is Tuesday, 10th January 2012, 5pm and the hardcopy with the signatures is Monday, 16th January 2012, 5pm. More information can be found on A*STAR's website at *www.a-star.edu.sg*.

2. Grand Challenges in Global Health – 2 Grant Programmes

The Grand Challenges in Global Health is a suite of grant programmes supported by the Bill & Melinda Gates Foundation. It is initiated with the aim to help promote the creation of new and better health solutions for the developing world.

There are currently 2 new grant programmes under Grand Challenges in Global Health, namely Discover New Ways to Achieve Healthy Growth and Preventing Preterm Birth.

(A) Discover New Ways to Achieve Healthy Growth Grant Programme

This grant programme seeks to discover new pathways or mechanisms that will aid the development of new interventions to prevent intrauterine growth restriction (IUGR), stunting, and wasting of newborns and infants in the developing world.

Eligibility
Applicant organizations must be individual non-profit organizations, for-profit companies or other recognized institutions that can successfully achieve the objectives of the grant programme.

Funding
The budget for each application will be capped at US$2million. A total of US$15million will be available to fund applications for this grant programme.

Submission & Deadline Details
A Letter of Inquiry (LOI) must be submitted by Wednesday, 25th January 2012, 10:00 am Pacific Standard Time. Short-listed applicants will be invited in March 2012 to submit a full proposal. More information can be found at *www.grandchallenges.org*.

(B) Preventing Preterm Birth Grant Programme

This grant programme seeks to generate new discoveries for more rapid development of equitable, relevant, and innovative interventions to prevent preterm birth and stillbirth in the developing world.

Eligibility
Applicant organizations must be individual non-profit organizations, for-profit companies or other recognized institutions that can successfully achieve the objectives of the grant programme.

Funding
The budget for each application will be capped at US$2million. This grant programme is expected to fund 6 to 10 applications.

Submission & Deadline Details
A Letter of Inquiry (LOI) must be submitted by Tuesday, 31st January 2012. Short-listed applicants will be invited in March 2012 to submit a full proposal. More information can be found at *www.gapps.org*.

3. NMRC & BMRC Joint Bedside & Bench Grant

The National Medical Research Council (NMRC) and Biomedical Research Council (BMRC) have launched a joint Bedside & Bench grant which aims to create a larger and more diverse base of research teams comprising basic and clinical scientists working together. The joint grant aims to translate scientific discoveries in the laboratory to clinically useful and commercially viable applications to improve health outcomes.

Eligibility
Each proposal must have at least 1 Clinician Scientist lead-PI, and 1 Basic Science lead-PI from BMRC or from the extramural community. Details for the individual lead-PIs may be found on NMRC's website.

Funding
The budget for each project will be capped at S$2 million, with additional 20% indirect costs provided to the host institution of the non-BMRC Basic Science lead-PIs. Additional funding of up to S$3 million, inclusive of 20% indirect costs, may be provided by the BMRC for proposals involving a scientist from the BMRC research institutes or units. The maximum funding duration for each project is 3 years.

Submission & Deadline Details
A letter of Intent (LOI) must be submitted to NMRC by Monday 16th January 2012, 5pm. More information can be found on NMRC's website at *www.nmrc.gov.sg*

4. NMRC TCR Flagship Programme

The TCR Flagship Programme seeks to integrate, coordinate and leverage on the full spectrum of research capabilities in Singapore from basic science to clinical research. It also aims to fund proposals that will draw on the strengths from institutions across Singapore with the relevant expertise. Existing TCR Flagships can also compete for funding renewal.

Eligibility
Eligible institutions for the TCR programme will include public sector hospitals and national disease centres, as well as universities. Each application will require a well qualified Clinician Scientist lead-PI to oversee and coordinate the implementation of the entire proposed programme for the institutions. Details for the Clinician Scientist lead-PI may be found on NMRC's website.

Funding
There will be 2 tiers of funding. The "Tier 1" Flagship Programme will be funded up to S$9 million and "Tier 2" up to S$25 million, both inclusive of indirect costs and over a period of 5 years. The final amount of funding allocated to the application will be determined by the scale, nature and quality of the research activity.

Submission & Deadline Details
A letter of Intent (LOI) must be submitted to NMRC by Monday 16th January 2012, 5pm. More information can be found on NMRC's website at *www.nmrc.gov.sg*

5. Venerable Yen Pei-National Kidney Foundation (NKF) Research Fund

The Venerable Yen Pei-National Kidney Foundation (NKF) Research Fund is started specifically to fund research in kidney diseases. The acceptable areas of research are basic science and clinical research that are of renal or renal related projects. If the research has relevance to NKF activities, the proposals would be considered as well.

Eligibility
The Principal Investigator must be a Singaporean or Permanent Resident, and should possess a minimum academic qualification of PhD and/or MBBS/BDS/MD.

Funding
The maximum funded amount for each project is S$300,000 for up to 3 years. The areas of research support that will be provided for are manpower, equipment, material & supplies and miscellaneous.

Submission & Deadline Details
The grant call will be open in January 2012. More information on deadline submission, please visit NKF's website at *www.nkfs.org*

Inaugural Collaboration for NTU and NHG: NTU-NHG Innovation Seed Grant 2011

The NTU-NHG Innovation Seed Grant was launched on 22 August 2011. It was an inaugural joint grant call by Nanyang Technological University (NTU) and National Healthcare Group (NHG) to fund collaborative projects in various aspects of medical innovation and improvement.

With the joint grant, both NTU and NHG hope to promote greater research collaborations between each other, and provide seed funding for potential projects to prepare for larger national grants.

The grant call was opened for 6 weeks from 22 August 2011 to 30 September 2011, and each application was jointly submitted by a Clinical-Principal Investigator from NHG and a Technical-Principal Investigator from NTU's College of Engineering.

After a rigorous short-listing process by the NTU-NHG Review Committee, the results were released in early November 2011. A total of 11 applications were selected for funding.

To commemorate the first NTU-NHG joint grant, 22 successful applicants were awarded at the Clinician Leadership in Research (CLR) and NTU-NHG Innovation Seed Grant Awards Ceremony held on 12 November 2011 at Suntec Convention & Exhibition Centre.

The Guest-of-Honour and award presenter to grace the occasion was Professor Stephen Smith, Vice President (Research), NTU and Founding Dean of Lee Kong Chian School of Medicine.

Results for the NTU-NHG Innovation Seed Grant 2011 can be found on NHG Research Website at *www.research.nhg.com.sg*

Review Committee & Awardees of the NTU-NHG Innovation Seed Grant

Certified Clinical Research Professionals (C.C.R.P.) Examination Preparation and Review Course

The purpose of this workshop is to assist the participant in preparing for the Society of Clinical Research Associates (SoCRA) examination for the Certified Clinical Research Professional (C.C.R.P.) examination and to review regulations, policies, and procedures appropriate to the clinical research environment.

The goal will be accomplished through lecture, discussion and practical application facilitated by certified clinical research professionals with combined clinical research experience of more than 20 years.

Information will be presented and discussed regarding the conduct of clinical trials; regulatory guidelines regarding IRB oversight and human research protections; ethical issues in clinical research; and workshops will stress the ability to follow directions and practices related to abstracting information and completing case report forms and other records.

To register for this 1-day course and/or to find out more, please proceed to *www.research.nhg.com.sg* (Training & Education -› Search for a Course)

For more info on SoCRA, please visit *www.socra.org*

NHG Research Training Calendar

for January - March 2012

Date	Time	Training Programme	Course Category	Module	Venue	Seats
Ongoing	00:00am-11:59pm	Proper Conduct of Research Online – Basic I-III	Proper Conduct of Research	PC101-103	www.elearning.nhg.edu.sg	120
30-31 Jan	09:15am-06:00pm	Singapore Guideline for Good Clinical Practice			National University Hospital, Kent Ridge Wing Level 2, ASTC, STLab	30
02 Feb 03 Feb 06 Feb	01:15pm-05:30pm 08:30am-05:30pm 08:30am-05:30pm	Biostatistics Workshop	Research Methodology		TBC	30
03 Feb	09:00am-06:00pm	Proper Conduct of Research Advanced II	Proper Conduct of Research	PC302	TBC	30
17 Feb	09:00am-06:00pm	Proper Conduct of Research Intermediate I	Proper Conduct of Research	PC201	National University Hospital, Kent Ridge Wing, Level 2, ASTC, STLab	30
07 Mar	09:00am-06:00pm	SoCRA Examination Preparatory and Review Course			Grand Copthorne Waterfront Hotel, Singapore	
07-09 Mar	09:00am-06:00pm	Asia Pacific Research Ethics Conference (APREC)			Grand Copthorne Waterfront Hotel, Singapore	

Results of the 2nd Singapore Health and Biomedical Congress (SHBC) 2011 Scientific Competition

The 2nd Singapore Health & Biomedical Congress (SHBC) Scientific Competition received a total of 334 abstracts from over six institutions within Singapore as well as submissions from overseas.

Unlike previous years, the judging component was held in the institutions of the main and co-organisers this year. From 31st October to 3 November, finalists presented their top-scoring abstracts to a distinguished panel of judges. Support from staff within the institution was evident from the encouraging number of audience present at the judging sessions. With the successful conclusion of the Congress we would like to extend our heartiest congratulations to the winners of this year's Scientific Competition!

Singapore Clinician (Investigator Award)	
Gold:	Dr Sim Kang, Institute of Mental Health
Silver:	Dr Colin Tan, Tan Tock Seng Hospital
Bronze:	Dr Jimmy Lee, Institute of Mental Health Dr Yang Peiling Samantha, National University Hospital Dr Lim Kenghua, Singapore General Hospital
Singapore Allied Health Award	
Gold:	Ms Lim Su Lin, National University Hospital
Silver:	Ms Dong Yanhong, NUS Yong Loo Lin School of Medicine
Bronze:	Ms Louisa Tan, National University Hospital
Singapore Nursing Award	
Gold:	Ms Rajni Parasurum, Institute of Mental Health
Silver:	Ms Jamie Lim, Tan Tock Seng Hospital
Bronze:	Ms Ng Hui Leng Isabel, Tan Tock Seng Hospital
Singapore Young Investigator Award (Basic Science/ Translational Research)	
Gold:	A/Prof Chu Jang Hann Justin, NUS Yong Loo Lin School of Medicine
Silver:	Dr Rufaihah Abdul Jalil, NUS Yong Loo Lin School of Medicine
Bronze:	Dr Chen Huijia, Institute of Medical Biology, A*STAR
Singapore Young Investigator Award (Clinical Research)	
Gold:	Ms Charis Kum, Tan Tock Seng Hospital
Silver:	Dr Chua Tjun Huat Ivan, Tan Tock Seng Hospital
Bronze:	Mr Jonathan Gwee, NUS Yong Loo Lin School of Medicine
Singapore Young Investigator Award (Quality & Health Services Research)	
Gold:	Dr Sun Yan, NHG HQ
Silver:	Ms Louisa Picco, Institute of Mental Health
Bronze:	Dr Milton Chew, NHG Eye Institute

SHBC Best Poster Award (Allied Health)	
Gold:	Dr Sherry Ho Sze Yee, National University Hospital
Silver:	Ms Tee Lee Huan, Tan Tock Seng Hospital
Bronze:	A/Prof Sharon Sung, Institute of Mental Health
SHBC Best Poster Award (Basic Science/ Translational Research)	
Gold:	Mr Mads Sylvest Bergholt, National University of Singapore
Silver:	Dr Xie Zhigang, National University of Singapore
Bronze:	Mr Melvin Wong, Khoo Teck Puat Hospital
SHBC Best Poster Award (Clinical Research)	
Gold:	Mr Lee Wai Kit, James, Tan Tock Seng Hospital
Silver:	Mr Ian Tay, NUS Yong Loo Lin School of Medicine
Bronze:	Dr Said Noor Hanif, National Skin Centre
SHBC Best Poster Award (Nursing)	
Gold:	Ms Li Ziqiang, Institute of Mental Health
Silver:	Ms Chan Mei Fong Carolyn, NHG Polyclinics
Bronze:	Ms Gan Chen Chen, Tan Tock Seng Hospital
SHBC Best Poster Award (Quality & Health Services Research)	
Gold:	Mr Teo Wee Sheng Kelvin, NHG HQ
Silver:	Dr Ding Ying, National University Hospital
Bronze:	Mr Wee Liang En, NUS Yong Loo Lin School of Medicine

Guest of Honor, Minister for Health, Mr Gan Kim Yong presenting the gold award of Singapore Clinician-Investigator Awards 2011 to Dr Sim Kang, Institute of Mental Health

Singapore Health & Biomedical Congress (SHBC) 2011 at a Glance

The 2nd Singapore Health & Biomedical Congress (SHBC) 2011 was successfully held on 11 & 12 November at the Suntec Singapore International Convention and Exhibition Centre.

Organised by NHG and co-organised by Alexandra Health Pte Ltd, Changi General Hospital and Jurong Health Systems, the Congress had welcomed more than 2200 participants with the theme - "Shaping our Regional Healthcare System – Innovation, Education, Research". Being the highlight of the Congress, the SHBC 2011 Scientific Competition received a total of 334 abstracts from over six institutions within Singapore as well as submissions from overseas.

SHBC 2011 Organising Committee Chairman, Associate Professor Thomas Lew (second from the right) with welcoming party receiving invited guest

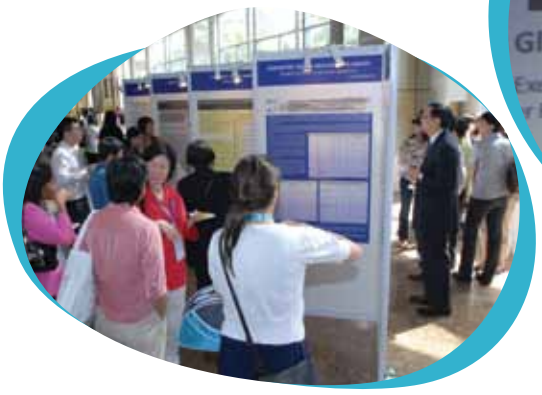
Opening Ceremony of SHBC 2011

Opening speech by Professor Chee Yam Cheng, Chief Executive Officer, National Healthcare Group

Dr Leong Khai Phang – SHBC 2011, Scientific Committee Chairman delivering citation for Keynote Speaker - Dr Glenn Steele

Professor Satkunanantham S/o Kandiah, Director of Medical Services, Ministry of Health, presenting the gold award of Singapore Young Investigator Awards 2011- Quality & Health Services Research to Dr Sun Yan, National Healthcare Group HQ

SHBC 2011's exhibition at Suntec Concourse



Poster Display at SHBC 2011

Keynote - Dr Glenn Steele, President and Chief Executive Officer, Geisinger Health System, receiving his token of appreciation from Mdm Kay Kwok, Chairman, National Healthcare Group

Delivery of the Plenary Lecture on "Vertical Integration of Regional Healthcare Systems: A Singapore Perspective" by Professor Philip Choo

Plenary Lecture on "Why the Early Environment Matters – Epigenetics, Evolution, Development and Disease" by Professor Peter Gluckman

Plenary Speaker, Professor Freddy Boey on "Biodegradable Cardiovascular Implants"

Plenary Speaker, Professor Stephen Smith in panel discussion on "Impact of Research and Education on Clinical Care in Developed and Developing Healthcare Systems"

Panel discussion with Plenary Speaker, Professor William Nelson on "Using New Technologies to Understand the Pathogenesis and Management of Prostate Cancer"

Plenary Topic on "Innovation is Coming: Will We be Its Leaders... Or Its Victims?" shared by Professor Elizabeth Armstrong

Question & Answer session after breakout session

Active breakout session in SHBC 2011

Active delegate of SHBC 2011

SHBC 2011's exhibitor with delegate at Suntec Concourse

Happy delegates of SHBC 2011

NHG RESEARCH QUALITY MANAGEMENT PROGRAM

QUALITÉ

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

ISSUE 2011/12

THE PRINCIPAL INVESTIGATOR'S ROLES & RESPONSIBILITIES (Part 5/5 series)

No.7: Ensure that the Investigational Product is Properly Administered and Stored

No.8: Direct all Relevant Site Operations

NON-COMPLIANCE REPORT

Lapse in renewal of Clinical Trial Certificate (CTC) and delay in reporting of the Non-Compliance event to the Domain Specific Review Boards (DSRB)

THE PRINCIPAL INVESTIGATOR'S ROLES & RESPONSIBILITIES

The Principal Investigator (PI) is responsible for the Investigational Product (IP) accountability at the trial site. This includes ensuring proper usage and storage of the IP. The investigator can familiarise himself or herself with the use of the IP through reading the product information leaflet or the Investigator's Brochure.

Protect the Rights and Welfare of Research Participants

Approval for Conduct of Research

The Principal Investigator (PI) has the responsibility of protecting the rights and welfare of the research participants throughout their involvement in a research study.

Prior to the commencement of any research study involving human subjects or use of human data, it is always necessary to ensure that approval from the Domain Specific Review Board (DSRB) is obtained. For research studies involving medical drugs and devices, approval from the Health Sciences Authority (HSA) is required.

Informed Consent from Participants

Before a research participant can be enrolled into the study, informed consent must be obtained from him/ her. The informed consent document should contain the elements required by the DSRB, and these elements are outlined in the DSRB Investigators' Manual Chapter 8.1-Informed Consent. When conducting the informed consent process, it is imperative that the language used is one that is understood by the participant. Study-related procedures, including screening tests, can only be carried out after informed consent has been obtained from the participant.

After sufficient time and opportunity have been given to discuss the research study and to address the concerns of the participant, the informed consent document shall be personally signed and dated by the research participant and by the person obtaining the consent. In most cases, the informed consent is obtained by the PI or by a Co-Investigator (Co-I) authorised by the PI to do so. Thereafter, a copy of the signed and dated informed consent document (information sheet and consent form) shall be provided to the participant. It is important to note that only the person conducting the informed consent can sign on the consent form.

If new information becomes available during the course of the research study that may be relevant to the participant's willingness to continue participation in the study, the participant should be informed in a timely manner. An example of such information would be new side-effects associated with the use of an investigational product.

Participants who are unable to read

In situations where the participant is unable to read, the PI has to secure an impartial witness for the entire conduct of the informed consent process and to ensure that the participant is properly informed of all aspects of the research study. An impartial witness is a person who is independent of the research study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the participant cannot read, and who reads the informed consent document and any other written information supplied to the participant.

Legally Acceptable Representative

A Legally Acceptable Representative (LAR) may give consent on behalf of an individual for participation in a research only when the individual is not capable of giving legally effective informed consent, such as in the case of a child, an individual who is cognitively impaired, or an individual who is unconscious. A LAR may be the spouse, parent, guardian (if there is no parent), person having charge of the individual, or person authorised by state law to consent on behalf of the individual. When consent is obtained from the LAR, the above-mentioned requirements must continue to be observed.

Research Involving Children

For research involving children (below 21 years), the person conducting the consent discussion should ask the child whether or not he or she wishes to participate in the research. This is out of respect for children as developing persons. In general, the DSRB requires that assent be obtained from children who are six years and above. The assent document should be submitted for DSRB's approval prior to being used.

Participant's Privacy and Confidentiality

As research studies may involve the collection of confidential and sensitive patient information, care must be taken to ensure that the participant's privacy and confidentiality are protected. A common practice amongst researchers is to use subject identification codes on data collection forms instead of using participants' actual names. A subject identification log may be used to document the link between the codes and the participants' identifiable information, and the log should be kept separate from the data collection forms and stored in a secure location.

Reporting Adverse Events

During the course of the research, adverse events may arise. When unanticipated and related adverse events or problems are discovered, they shall be promptly reported to the DSRB and the HSA (if applicable). Unexpected Serious Adverse Events (SAE) that are life-threatening or results in death shall be reported immediately to the DSRB, the HSA and the sponsor. Reporting timelines for adverse events may be found in the DSRB Investigators' Manual Chapter 4.4-UPIRTSO and on the HSA website.

References:

- *Singapore Guideline for Good Clinical Practice (SG-GCP)*
- *NHG Proper Conduct of Research SOP 501-A02 Responsibilities of the Research Team*
- *NHG Proper Conduct of Research SOP 501-C01 Informed Consent Document and Process*
- *NHG Proper Conduct of Research SOP 501-C01 Unanticipated Problems Involving Risks to Subjects and Others*

Ensure Documentation of Study Related Procedures and Events

The Principal Investigator (PI) assumes the responsibility to ensure that study-related procedures and events are properly documented and essential research documents well-maintained.

Documenting Informed Consent

Both the person conducting the consent procedure and the subject (or the subject's legally acceptable representative) should sign and date on the Informed Consent Form (ICF), as a form of documentation that informed consent has been obtained prior to the subject's participation. For studies involving access to subjects' medical records, information about the consent process, such as the study title, date of consent and the fact that a copy of the ICF was given to the subject, should also be documented in the medical records by the person who conducted the consent procedure.

Recording Research Information and Documenting Changes to Data and Case Report Forms

Prior to study initiation, the PI and the study team should agree upon the source documentation required for the study. The PI should also ensure the accuracy, completeness, and legibility of recorded research information and data reported in the Case Report Form (CRF). The data in the CRF must be consistent with the source documents and any discrepancies should be explained. Changes or corrections to the CRF should be made by crossing out the original entry with a single line without obscuring the original data. The correct entry should then be written near the original entry. The change should also be dated, initialed, and explained (if necessary). This is to ensure that the recorded study information will allow for accurate reporting, interpretation and verification.

Documenting Adverse Events

The PI is responsible for ensuring that all study-related adverse events and the management of these events are accurately documented in the medical records. Documentation should include details, causality, severity, date of onset, end date, treatment provided and outcome of the event.

Documenting Deviations

Any protocol deviation(s) from the approved protocol, during the course of the study (except to eliminate any immediate hazard(s) to the subject), should be adequately documented. The agreement by the sponsor and necessary Institutional Review Board (IRB) documented approval should also be obtained prior to implementing the deviations.

Documenting Premature Un-blinding of Investigational Product

For blinded studies, any premature un-blinding of the investigational product (e.g. accidental un-blinding, un-blinding due to a serious adverse event) should be well-documented with explanation provided for the premature un-blinding.

Providing Study Reports According to Requirements

It is the PI's responsibility to provide any written reports on changes significantly affecting the conduct of the trial and/or increasing the risk to subjects, study status reports or study completion reports, as requested by sponsor, DSRB and HSA.

Ascertaining the Reason for Subject's Premature Withdrawal

In the case of a participant's premature withdrawal from the study, the investigator should make a reasonable effort to ascertain the reasons for the withdrawal (while respecting the participant's rights) and the reasons recorded in the Subject Enrolment Log and the subject's medical notes.

Maintenance and Retention of Research Documents as Per Requirements

During the course of the study and throughout the period required for its retention, PI is responsible for ensuring that all essential documents are maintained. According to MOH guidelines, inactive medical records are culled. Hence, to enable retention of these medical records, the PI must indicate on the cover of the medical records, the retention requirements of the trial, so as to prevent accidental or premature destruction of these documents. The PI (with help of the clinical research coordinator) must also arrange for archiving of all other essential study documents in a secure location that is access controlled. Information regarding the period of time required for retention of these documents can be found in SGGCP Section 4.9.6.

References:

- *Singapore Guideline for Good Clinical Practice (SG-GCP)*
- *NHG Proper Conduct of Research SOP 501-A02 Responsibilities of the Research Team*
- *NHG Proper Conduct of Research SOP 501-B05 Documentation*

Non-Compliance Report

Lapse in renewal of Clinical Trial Certificate (CTC) and delay in reporting of the Non-Compliance event to the Domain Specific Review Boards (DSRB)

All research studies involving investigation of medicinal products will require a Clinical Trial Certificate (CTC) issued by the HSA. The CTC has an approval period of 2 years, and renewal is required at the end of the 2 year period if the trial is to continue.

In a recent case of a reported non-compliance, the sponsor of a particular vaccine trial failed to renew the CTC for the ongoing study. The Clinical Research Associate (CRA) designated to manage the CTC application and renewal was on a 4-month maternity leave. Although there was a backup CRA assisting the site with the trial during this period, the backup CRA did not have the necessary access to renew the CTC. Thereafter, the CTC approval lapsed.

During the lapse period, there was 1 subject on treatment. The other subjects who were enrolled in the trial had completed the treatment before the lapse occurred. The CTC was eventually renewed when the CRA returned from her maternity leave.

The incident was notified to the DSRB only 4 months after the lapse of the CTC approval. As this incident was not promptly informed to the DSRB, a warning letter was sent to the PI to remind the PI of his responsibilities to ensure ongoing regulatory and ethics approval and timely protocol deviation or non-compliance reporting.

All Principal Investigators, Clinical Research Associates and Clinical Research Coordinators are reminded to ensure that continuing approvals from the HSA and the DSRB are maintained throughout the course of the research study.

For Investigator-Initiated trials, the PI assumes the overall responsibility and oversight at the trial site including that of the sponsor to ensure that both regulatory and ethical approvals are maintained throughout the study.

Should a non-compliance be detected, the investigator should adequately document the occurrence and promptly report them to DSRB via the NHG Research Online Administration & Management (ROAM) system with a completed Protocol Deviation Form within 7 calendar days. Details of the non-compliance, together with the necessary corrective actions taken, should be included in the reporting of this event to the DSRB. The sponsor should also be notified as soon as possible.

In general, it should be noted that no procedures or collection of data for research purposes should be carried out when the approval from DSRB or HSA has expired, or when there is a lapse in the renewal of these approvals.

The Catalyst Editorial Team wishes all readers a Merry Christmas and a Happy New Year.

From left to right:

Yeo Kian Wah, Choo Kin Poo, Adam Koh, Loi Mee Mum, Wenald Loh, Valerie Wee, Chen Siya, Claudine Teo, Ng Hwee Hian, Clara Lim, Doreen Lim, Felicia Wong, Melody Teo, Kristen Guo

Absent:

Fatimah Begum Bte Mohamed Muneer, Lynnette Wang, Norsalleha Bte Salim, Siti Zawiyah, Jac Ang, Nursaleha Razelan, Evelyn Teo

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Ezekiel J. Emanuel, MD, PhD

Diane v.S. Levy and Robert M. Levy University Professor and Vice Provost for Global Initiatives, University of Pennsylvania

Special Advisor for Health Policy to Director of White House Office of Management and Budget

Distinguished Keynote Speakers

Prof Johan P.E. Karlberg

Founder, Managing Director, Clinical Trial Magnifier Limited
Consultant, UNIMED Medical Institute

Prof Toshiaki A. Furukawa

Professor and Chair, Department of Health Promotion and Human Behaviour, Kyoto University Graduate School of Medicine/ School of Public Health

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