

catalyst



ACCELERATING RESEARCH

A NEWSLETTER FOR THE RESEARCH COMMUNITY IN SINGAPORE

APR/MAY 2012
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National
Healthcare
Group

Adding years of healthy life



COLLABORATIVE RESEARCH

**EXCLUSIVE
INTERVIEW**
Dr Stephen Teoh
NHG Eye Institute



EVENT HIGHLIGHTS

**ASIA PACIFIC
RESEARCH ETHICS
CONFERENCE 2012**



CLINICAL RESEARCH

HELPFUL RESOURCES
Health Sciences Authority



SPECIAL FEATURE

DR STEPHEN TEOH
Head of Research
NHG Eye Institute

contents

FEATURE

Special Feature

- 14 Knowing Our Healthcare Leaders

RESEARCH

Clinical Research

- 4 Small Innovative Grant I (SIG I) Awardee
- 5 Polypoidal Chorioidal Vasculopathy (PCV)
- 6 A Tribute to Allied Health Professionals

Research Industry

- 7 A Philosophy of Research Support
- 8 GCP Inspections
- 9 NHG's Inaugural Intellectual Property Course
- 22 NHG FY2012 Grant Results
- 24 Upcoming Grant Calls

Research Education

- 3 RDO - A WDA ATO
- 10 A chat with SoCRA Proctor
- 12 SoCRA C.C.R.P Certification Examinations
- 13 Introducing the Resources Page
- Responsible Conduct of Research (RCR)
- 16 DSRB Domain F
- GCP Teasers
- 17 Proper Conduct of Research
- 18 Useful Websites
- Helpful Resources
- 25 Qualité

EVENTS

Event Highlights

- 19 Asia Pacific Research Ethics Conference 2012
- 21 19th Clinical Research Coordinator Society Forum
- Research Leadership & Management Forum

Upcoming Events

- 28 NHG Research Training Calendar

from the editor-in-chief

Dear Readers

As the newly appointed editor-in-chief for Catalyst, I would like to express my thanks for your continuous support and feedback that has enabled us to develop the preferred research newsletter for you.

I am pleased to update that only into the second quarter of 2012, our NHG Research & Development Office (NHG RDO) records two major achievements. The first for successfully organizing the 2nd Asia Pacific Research Ethics Conference (APREC) in collaboration with the Public Responsibility in Medicine & Research (PRIM&R) (United States) on 7-9 March 2012. The conference saw a healthy turnout of 260 delegates and 85 speakers from Asia, Europe, Middle East, Australia and USA.

The other noteworthy achievement is the attainment of the status as a Singapore Workforce Development Agency Approved Training Organisation (WDA ATO). With this accreditation, NHG RDO is able to conduct clinical research training under the Clinical Research Singapore WSQ framework and issue nationally recognized certificates. This makes NHG the only healthcare institution to have achieved this. It also affirms our commitment to conduct quality clinical research training for our research community.

Continuing with our theme of Collaborative Research, this edition of Catalyst features Dr Stephen Teoh, Head of Research and Consultant at the National Healthcare Group Eye Institute who shares with us his thoughts on the topic. Also featured are articles contributed by our past Small Innovative Grant (SIG) and Clinician Leadership in Research (CLR) awardees. We are also pleased to announce the FY2012 SIG I and CLR awardees. Our heartiest congratulations to them!

I trust that you will find this edition of Catalyst enjoyable and informative.

Yours Sincerely

Farah

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's Research and Development Office is now a WDA Approved Training Organisation (ATO)!

As a Singapore Workforce Development Agency (WDA) Approved Training Organisation (ATO), National Healthcare Group (NHG) Research & Development Office (RDO) will be able to conduct Clinical Research training under the Singapore Workforce Skills Qualifications (WSQ) Clinical Research framework and issue nationally recognised WSQ certificates.

The accreditation is a testament to the quality of NHG's training, and its ability to deliver industry validated and endorsed competency-based training.

The accreditation of Proper Conduct of Research (PCR) Basic will allow many Clinical Research Coordinators (CRCs)

and Clinical Research Associates (CRAs) to be trained under NHG RDO and be equipped with nationally-recognised skills. These skills will allow them to perform their jobs more effectively and efficiently, resulting in a more fulfilling career progression pathway in the healthcare industry.

With NHG's capable and competent trainers, these accredited PCR courses will enhance the quality of how clinical research is conducted in Singapore, clearly emphasising on human subject protection and also, to provide advice on the future development of programmes relating to clinical research.

One of the only institutions to be awarded the title of WDA ATO in the healthcare industry, NHG sets the standards of research training, promoting high standards of research conduct.

The higher level of credibility that comes along with it, will open up the doors to more opportunities in clinical trials and attracting various research grants in the different areas.

Providing you with Nationally Recognised Clinical Research Training



We are proud to announce that "Proper Conduct of Research (PCR) Basic – PC102" developed by National Healthcare Group (NHG) Research & Development Office (RDO) has successfully been accredited under the WSQ Clinical Research framework in March 2012.

NHG RDO will work with WDA to offer Proper Conduct of Research – Basic II (PC102) which is equivalent to the competency unit "WSQ Perform Recruitment and Retention of Subjects in Clinical Trials" under the WSQ Clinical Research Coordinator (CRC) Competency Map (level 2). Topics covered in this course are:

1. Employ Subject Recruitment Strategies and Proper Documentation in Subject Recruitment
2. Manage and Retain Subjects in Clinical Research

3. Support or conduct a proper Informed Consent Process
4. Alteration and Waiver of Informed Consent in Special Circumstances

Theoretical and practical knowledge on the strategies and challenges of subject recruitment and retention will be emphasized during the course; and hence, trainees will be able to apply their knowledge in their course of work. They will also be equipped with key principles of informed consent and conditions for alterations to informed consent to prepare them to support the investigator and perform proper informed consent discussions.

This course is delivered through online instructional lectures and trainer-led workshops, and consists of an assessment component.

Trainees will be awarded a Statement of Attainment (SOA) upon the completion of this unit.

This course will be officially launched in June 2012.

Find out more about NHG's accredited research training courses at www.research.nhg.com.sg (Training & Education > Search for a course).



Small Innovative Grant I (SIG I) Awardee

A/Prof Sim Kang
Consultant Psychiatrist
Deputy Director, Research Department
Institute of Mental Health

One of the most distressing symptoms is that of the passivity phenomenon whereby the patient with schizophrenia feels that his actions, thoughts, or emotions are being controlled by an external agent. This can create a great sense of fear, frustration, or unease in the patient which can predispose them to act out and commit acts of aggression.



“Through my interactions with the patients and family members during my clinical work, I have often wondered about the neural basis underlying symptoms that our patients come with.”

In the National Healthcare Group (NHG) Small Innovative Grant I (SIG I) study entitled “Parietal lobe structural and white matter abnormalities in schizophrenia with passivity phenomenon: A MRI volumetry and diffusion tensor imaging study”, we investigated the possible brain white matter abnormalities that may underlie this disabling symptom.

This work expands our earlier understanding based on data from two groups of investigators in UK and Australia. The UK team led by Professor Spence found functional brain hyperactivations associated with passivity and the Australian work by Professor Maruff observed reductions of brain volumes in parietal and frontal association cortices in patients with passivity symptom.

Extending this knowledge, our team found that underlying white matter changes occur in the inferior frontal gyrus, cingulate gyrus, basal ganglia and thalamus suggesting a distributed involvement of cortical and subcortical regions associated with passivity with implications of white matter circuitry disruptions. More of such studies are needed but the accumulated information may hopefully allow us to better explain the causes of the symptoms to both patients and their caregivers.

I am thankful for the NHG SIG which allowed me to take a first step in elucidating brain changes in psychosis. These preliminary findings facilitated our subsequent clinching of a Singapore Bioimaging Consortium (SBIC)/A*STAR grant. The latter grant allows us to probe the changes in specific brain circuitries and also their relationships with genetic changes in psychosis.

In one of our more recent studies, we found that the presence of armadillo repeat gene deleted in velocardiofacial syndrome (ARVCF)-HAP1 haplotype is significantly associated with disrupted white matter integrity of the caudate nucleus and poorer executive functioning in patients with schizophrenia.

Currently, we seek to examine the relationship between genetic factors and manifestations of psychotic illnesses in terms of clinical symptoms, global functioning, brain imaging substrates and neurocognitive deficits. More refined delineation of these underlying biological factors (genetics, brain changes) can help us to better appreciate the causation of the illness, prognostic markers and biomarkers for intervention. We hope to expand such platforms of understanding to other psychiatric disorders such as mood disorders like bipolar disorder and depression.

Being part of a multidisciplinary team which is actively involved in the holistic care of patients in our busy ward, a better mechanistic understanding of these potentially crippling psychiatric conditions is especially meaningful for my team and me.

Albert Einstein was once asked the question “How do you work?” and he answered “I grope”. Indeed, it has been a steep learning curve for my team thus far but an extremely fulfilling journey. We are thankful for our colleagues/ collaborators from Institute of Mental Health (IMH), A*STAR, National University of Singapore (NUS) for their support and friendship. Despite challenges including the vagaries of funding, may Einstein’s words encourage us to persevere in our quest to further unravel the mysteries of these brain changes.



Polypoidal Choroidal Vasculopathy (PCV)

Dr Colin Tan
Consultant
Tan Tock Seng Hospital

Neovascular or wet age related macular degeneration (AMD) is one of the top four causes of blindness in Singapore. Polypoidal Choroidal Vasculopathy (PCV) is a subtype of wet AMD and has a higher prevalence among Asians. It occurs in 20% to 55% of Asian patients with wet AMD, compared to around 12% for Western populations.

Therefore, PCV is an important clinical condition to investigate in Singapore. This disease is characterised by the growth of abnormal blood vessels and polyps underneath the retina. These abnormal blood vessels may leak fluid or bleed, causing swelling and damage to the retina, which may result in permanent loss of vision.

Clinicians have long observed widely varying clinical behavior of PCV - from those that are benign and quiescent, to those that are aggressive and persistent. The former typically responds to focal, relatively inexpensive treatment such as laser photocoagulation, while the latter is best treated aggressively by combining different treatment modalities. However, there is no uniformly accepted classification system for PCV, partly because previous angiographic techniques did not give sufficient detail of the disease.

Our team from the National Healthcare Group Eye Institute (NHGEI) has described a novel classification system for PCV and found a correlation of these subtypes with the long term visual outcomes.

This research team consists of myself, A/Professor Lim Tock Han, Dr Ngo Wei Kiong, Dr Louis Lim, Dr Milton Chew and Dr Kelvin Li.

Using advanced angiographic techniques, which employed laser in a confocal scanning laser ophthalmoscope, we were able to obtain detailed images of the fine blood vessels which supply the polyps and contribute to the disease process.

Our study team then went on to identify and classify three distinct types of PCV. We reviewed 108 consecutive patients with PCV at the Department of Ophthalmology, Tan Tock Seng Hospital and monitored their clinical and visual outcomes over a 5-year period. By applying our classification system, we found that Type I PCV had the best long-term visual outcomes, with around 80% retaining good vision over a 5-year period. In contrast, Type II had an intermediate course, while Type III was the most aggressive, with many patients experiencing poor visual outcomes.



Dr Colin Tan is also a recipient of the Clinical Leadership in Research (CLR) programme for his research "Vascular patterns of polypoidal choroidal vasculopathy - An Asian perspective". He recently received the SHBC 2011 "Singapore Clinician-Investigator Award" for his poster entitled "A Novel Angiographic and Anatomic Classification of Polypoidal Choroidal Vasculopathy Predicts its 5-year Clinical Outcomes"

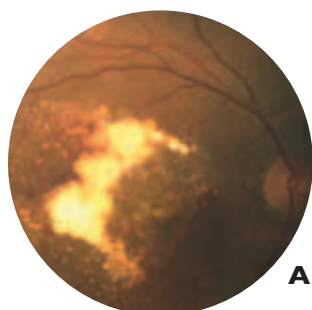


FIGURE A. Fundus photograph of a patient with PCV, showing extensive areas of bleeding and oedema (swelling) of the retina.

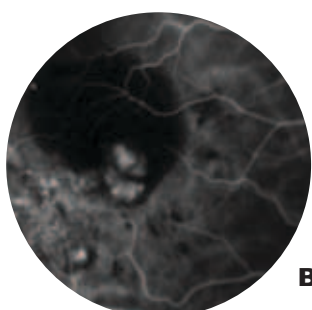


FIGURE B. Indocyanine green (ICG) angiogram showing the polyps and the abnormal blood vessels supplying the polyps.

"Our research is the first of its kind to establish a novel classification system for PCV. We have identified 3 subtypes of PCV with differing clinical outcomes. This classification system may aid in future prognosis of patients with PC and cost-effective management of this condition."



A Tribute to Allied Health Professionals

clinical research
RESEARCH

Ms Jaelyn Ong
Senior Clinical Research Coordinator
Institute of Mental Health



Ms Jaelyn Ong is a Senior Clinical Research Coordinator at Institute of Mental Health (IMH). She graduated with a Bachelor degree in Nursing and is part of the Association of Clinical Research Professionals (ACRP). Her experience ranged from research, project management to quality control. Prior to joining IMH, She was with MDS Pharmaceutical and Alexandra Hospital as a Research Nurse.

“In my current position, my key responsibilities include implementation of recruitment strategies, managing and coordinating clinical research trials activities and facilitating collaborations with key opinion leaders and health care professionals.”

What made you decide to dwell into research?

I wanted a career where I can feel like I am helping people and that led me to start my career as a staff nurse. After attaining my degree in nursing, my curiosity in diseases and drug development pushed me towards clinical research. I enjoy being involved in the entire process, from conducting clinical research to marketing (*I get to know the drugs long before anyone else!*). Working in a dynamic environment with researchers coming forth with new therapies and ideas also motivated me to pursue a career in research.

How do you feel about your research work together with other clinicians and PI(s) in the hospital environment?

There is mutual respect between the clinicians and the research coordinator. They are willing to guide you from the clinical perspective and I, too, guide them from the research perspective.

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

The patients – seeing them get well after taking the study drug and thanking you for helping them improve their lives. As a research coordinator, the trials in which I am involved in varies. One moment, I can be involved in a Schizophrenia study, while in the next, I may be involved in a depression study. My work varies a lot. It is dependent on which pharmaceutical company as well as the type of project I am handling.

What are your daily and greatest challenges faced in your job?

Performing recruitment and retention of mentally unwell patients. They need extreme discipline to return for appointments, and to convince them to participate in the clinical trial.

What do you enjoy least about your role, and how do you cope with it?

When the subject encounters a serious adverse event related to the study drug, I have to convince myself that it is unavoidable in clinical drug trials and there will be some subjects who benefit from it and some who do not. I will always remind myself to look at the bigger picture and that the trial has to move on and keep faith that one day it will become a noble drug which will benefit many.

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

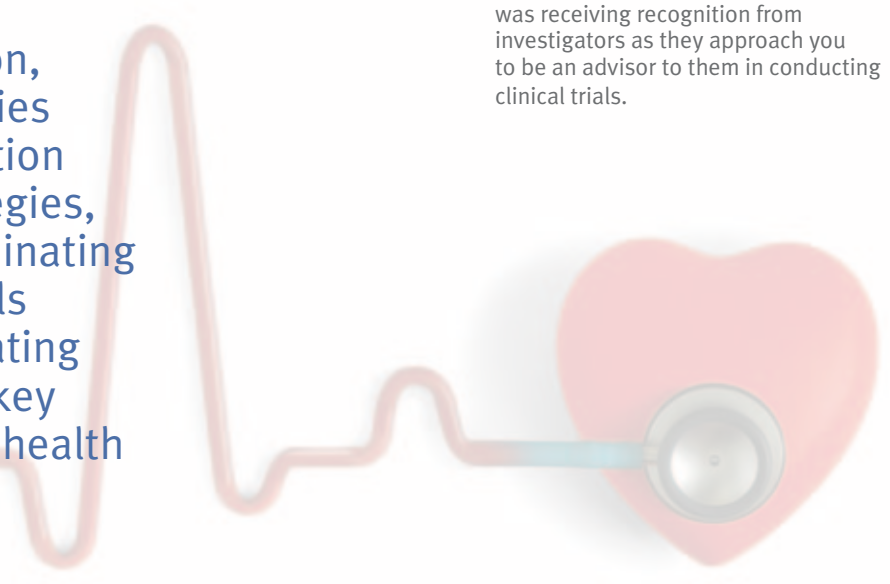
The greatest satisfaction about my job is to be able to watch patients recovering from the study drug as it motivates me to continue and stay in this career and my role as a coordinator.

How do you handle the tight demands of your schedule?

Planning and prioritization are very important skills I used to handle tight demands of my schedule.

Was there a rewarding / memorable moment that you could share with us?

One of the most rewarding moments was receiving recognition from investigators as they approach you to be an advisor to them in conducting clinical trials.





A Philosophy of Research Support

Dr Leong Khai Pang
Senior Consultant
Tan Tock Seng Hospital



Dr Leong Khai Pang (top row, third from left), with his team at Tan Tock Seng Hospital

Let us reason, from first principles, how a healthcare organisation should support research. We assume that the organisation truly believes in the benefits conferred by a research programme, such as intellectual rigour, educational prowess, staff development and satisfaction, or else our subsequent arguments are irrelevant.

There are opposing forces at play. The organisation must practice fiscal prudence because public funds must support many worthwhile healthcare efforts besides research. Research costs money, sometimes significantly so, and it is, by definition, unpredictable, so no one can tell who or which project will be successful at the outset.

What are the responsibilities of the organisation? It should support the most promising projects, but does not know which at the beginning. It is accountable for the use of funds and will require some measurable quantities to determine the returns.

The organisation is cognisant that there are competitive grants offered by external agencies meant for specific projects.

What are the characteristics of research and researchers? Seemingly unimportant projects may turn out to be landmark achievements. No researcher starts out thinking that he will be a failure; there must be a reasonable trial period for him to prove his mettle. Researchers only have a short active creative life, perhaps 15 to 20 years. Research can move very fast, and what is novel today can become public-domain knowledge tomorrow. Researchers are subject to a punishing 3-year cycle of writing grants, recruiting staff, actually executing the project, producing results, publishing and re-entering the loop.

Rather than restrict research to a few top-down pre-selected areas, the organisation should support a wide base of researchers at the outset and intelligently, responsibly but mercilessly winnowing out the unpromising ones quickly.

It must optimise the conditions for the researchers to win competitive grants, including providing for administrative research offices, statistical and grant-writing support. Once the grants are won, there must be a pre-built research infrastructure that will make use of the money quickly and efficiently. Laboratories, technicians, administrative support must be kept on retainer and be ready to be deployed quickly. Researchers should not have to build things from scratch each time they embark on a project; they must be able to exploit new opportunities quickly.

There are, thus, three areas of research support: infrastructure, talent development and project execution. The responsibility of the first lies almost entirely the organisation, the second lies on the organization's at the beginning of the researcher's career and on national funding agencies' subsequently while that of the third generally lies on the private and national funding agencies.

Understanding these conclusions leads to a reasoned and balanced funding structure.

GCP Inspections – Looking back at 2011

Ms Sumitra Sachidanandan
Compliance Inspector, Clinical Trials Branch,
Health Products Regulation Group,
Health Sciences Authority

The Health Sciences Authority (HSA) and the National Healthcare Group (NHG) hosted the Combined Clinical Research Professionals - Clinical Research Coordinator Society (CRP-CRCS) Forum at the National University Health System Auditorium on 12 Dec 2011. The theme of this forum was ‘GCP Inspections – Looking Back at 2011’.

Mr Foo Yang Tong (Director, Clinical Trials Branch, Health Products Regulation Group, HSA) shared about the Common GCP Inspection Findings noted from GCP inspections conducted in 2011 while Ms Sumitra Sachidanandan (Compliance Inspector, Clinical Trials Branch, Health Products Regulation Group, HSA) presented case studies on Informed Consent and Investigational Products based on the GCP Inspections.

The forum was attended by 300 clinical research professionals from pharmaceutical companies, Contract Research Organisations (CROs) and research institutions. Mr Foo shared that a total of 16 GCP Site Inspections had been conducted in 2011. See Fig. 1 for the distribution of the GCP inspection findings.

It was shared that there had been an increase in the percentage of critical and major GCP inspection findings and a decrease in other GCP inspection findings in 2011 in comparison to 2009-2010. Investigational Products, Informed Consent and Subject Recruitment accounted for the top three critical and major GCP inspection findings, whilst Investigational Products, Investigator’s Site File and Informed Consent accounted for the top three other GCP inspection findings.

In addition to GCP inspections, HSA also embarked on Quality Improvement initiatives in 2011 such as uploading Frequently Asked Questions on

Classification of GCP Inspection Findings

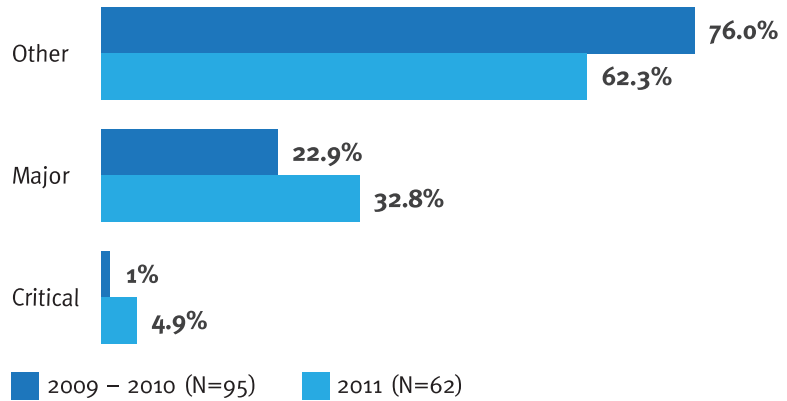


Fig.1: Classification of GCP Inspection Findings (2011 vs 2009-2010)
(Source: Health Sciences Authority)

the HSA website, meetings with healthcare cluster’s Research Quality Assurance staff, observation of GCP site inspections by healthcare cluster’s Research Quality Assurance staff, generating quarterly newsletters entitled ‘From the GCP Inspector’s Desk’, and providing consultation on management of Investigational Products prior to HSA approval of the clinical trial, when required.

Ms Sachidanandan emphasized salient points on Informed Consent and Investigational Products management through case studies developed from GCP Inspections conducted in 2011. The forum noted that there is no legal provision for the use of Short Form Consent for clinical trials on medicinal products.

Hence, in the event a subject was unable to read the English Informed Consent Form and a corresponding translated Informed Consent Form was unavailable, the investigator should explain the English Informed Consent Form to the subject in the presence of an impartial witness in accordance with Medicines (Clinical Trials) Regulation 11(5) and SGGCP 4.8.9.

The impartial witness should attest that the Informed Consent Form had been accurately explained to the subject, apparently understood by the subject and the subject had voluntarily agreed to participate in the clinical trial. It was reiterated to the audience that the impartial witness should be independent of the study team.

Ms Sachidanandan also presented a case study on Investigational

Product management where the site had been involved in re-packaging of the Investigational Products for a randomized, double-blind, placebo-controlled clinical trial. The process of re-packaging the Investigational Products was equivalent to a secondary assembly process, and thereby the inherent need to comply with Good Manufacturing Practice (GMP) requirements.

The GMP requirements for re-packaging as outlined in Sections 23 to 25 of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme (PICIS) Annex 13 were reviewed in the forum.

Materials presented at this forum can be found on the HSA website at www.hsa.gov.sg

“In summary, standard operating procedures, delegated and trained unblinded study staff, line clearance, label re-conciliation and documentation are required for re-packaging of Investigational Products.”



About NHG's Inaugural Intellectual Property Course

Ever wondered what Intellectual Property is about? Confused with the terminologies - patents and trademarks? The inaugural National Healthcare Group Intellectual Property Course was conducted on 23 March 2012 with the aim of introducing the concept of Intellectual Property.

Background

With Singapore increasingly becoming a popular destination for research and development initiatives and the government placing greater emphasis on research, the likelihood of new inventions and discoveries being made increases. In order for others to not leverage on you or your institution's new inventions and discoveries by stealing or plagiarising your ideas, some form of protection is required. The protection of new inventions, discoveries, ideas and formulae even, falls under the ambit of Intellectual Property protection.

Learning Objectives

Participants of the course took home three key learning objectives - understanding the various components of Intellectual Property; learning the rules, regulations & laws pertaining to Intellectual Property; and the process of filing a patent for new inventions.

The key topics covered in the Course

Introduction to Intellectual Property and what it protects:

This topic provided a brief introduction to the various aspects of IP namely - trademarks, copyrights, patents and what they protect. It also provided participants with an introduction to the Patent Cooperation Treaty and its effects.

The role of patents in the biomedical industry:

This topic explained the important role of patents in biomedical research and product development. It highlighted some practical measures for patent protection, as well as the strategies for effective enforcement of patent rights.

How to file a patent:

Participants learnt about the steps required in filing a patent. A hands-on session on filing a sample patent was conducted to allow participants to familiarise themselves with the procedures with participants.



Introducing Patents

A patent is not compulsory but is useful to ensure that your competition does not benefit from your original invention. If you wish to file the patent overseas, it then becomes a requirement for you to have your patent registered in Singapore with the Registry of Patents first before you can commence your application for patent protection overseas.

What is a Patent?

A Patent is a legal right given by the government to an inventor that protects him from people who use or replicate his invention without his consent.

What is Patentable?

Before anything can be patented, it needs to fulfill three major criteria:

- It has to be a new idea;
- It involves an inventive step; and
- It must have an industrial application.

Do note that new methods of surgery or therapy are not patentable.

Rights Conferred

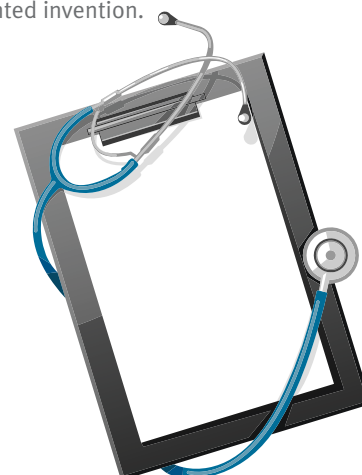
Essentially the right accorded to you when you successfully file a Patent is that you get to enjoy 20 years of exclusive use (from the date of filing the patent application) for your invention; no one is allowed to exploit your invention without first seeking your consent. Annual renewal fees are applicable.

Legislation

The legislation governing Patents in Singapore mainly comprises the Patents Act (Cap. 221), along with its subsidiary legislation, which includes the Patents Rules, the Patents (Patent Agents) Rules, and the Patents (Composition of Offences) Regulations.

Benefits of Registering a Patent

There are three main benefits to registering a Patent. They are – the ability to gain additional finances, the right to license your Patent to a third party and lastly, you can sell the patented invention.





A chat with SoCRA Proctor – Ms Susan Devine

Ms Susan Devine, CCRP
Senior Manager
Clinical Trial Support Unit
Hospital for Sick Children, Toronto



Ms Devine presenting in Singapore at the 19th Clinical Research Coordinator Society (CRCS) Forum on “Investigator’s Responsibilities – Managing Through Delegated Tasks”

Ms Susan Devine has been involved in pediatric hematology oncology and bone marrow transplant clinical trials for almost thirty years and has experience in all facets of clinical trial facilitation. Ms Devine is Chair of the Children’s Oncology Group (COG) CRA Discipline for 14 years, member of the COG Executive Committee for 10 years, member of the American Society of Clinical Oncology and a board member of the Society of Clinical Research Associates (SoCRA).

How is Responsible Conduct of Research practiced in your institution?

We (SickKids CTSU, Canada) have on site training and mentoring programs, SOPs and internal monitoring to help promote adherence to Good Clinical Practice (GCP) and regulations thereby supporting the Investigators with their responsibilities and sharing the load while maintaining patient safety and data integrity.

- On-site training lasts roughly about 6 months and consists of modules to train Clinical Research Associates (CRAs) through various processes, online databases and quizzes. They consist of good clinical practice training, which is the backdrop of enrolling patients and initiating studies; human subject protection and study specific training. It may also involve training within the hospital. These include electronic health system, internal database for lab results, safety pack training for shipping of specimens; ethical training; attendance at conferences; and reading up on certain diseases for the studies they are working on.
- Standard Operating Procedures (SOPs) for all the regulatory requirements and for managing studies. SOPs are also often used as a training tool, and as a reference.
- Mentoring programs allow persons more senior to act as mentors or point persons to new staff to help them.
- Internal monitoring program - Most of our studies are monitored on an ongoing basis, and are conducted approximately 6-8 weeks after the first enrolment on any therapeutic study. The reason is so that if we do make a mistake, we want to catch it and implement a change in the future. It is an additional work load, but it is cost-effective if we catch the mistake early on and it doesn’t get repeated.



What are some of the common challenges faced by clinical research staff assisting investigators and how can these be overcome?

The three biggest issues that we face are the lack of appropriate funding which is a universal problem; having tasks delegated to CRAs, where they are ill-equipped and not properly trained to manage them; and inattention of Principal Investigators (PIs) in some cases.

If you delegate a task to someone who is ill-equipped, you're creating problems for your study and you are not taking good care of patients' health. CRAs should be given the tools to do their jobs and good PIs and teachers are essential. It is important to get people who have the right backgrounds and provide a nurturing, kind mentorship, to help and teach them; and give them an ability to be comfortable asking questions. Study coordinators need to learn to speak up and not be afraid to ask a question, because if they don't ask, they could guess wrong.

The inattention of PIs is sometimes a little more difficult to manage. Try setting up a regularly scheduled meeting, even if it's only for 20 minutes once every 3-4 weeks. The CRA should go with very directed questions, a report detailing the studies' progress and all supporting documentation. They should be proactive by bringing good specific examples of issues and stating when there are no issues. This is what I teach my team, and they become more successful. This is because the PI will come to rely on you and respect what you know. What's more, it will establish that when you do ask a question, it's because you don't know the answer and it is important for them to intervene. If that doesn't work and you are not able to get the PI to be supportive of you in some way, sit them down and tell them you are not able to support them properly.

Finally, when patient safety is being jeopardized or when GCP is not being followed, CRAs need to speak up. It is hard, because there's a sense amongst some coordinators that they might lose their job. However, it is important because coordinators are the ones who will see and know it first.

How can Clinical Research Professionals (CRPs) better equip themselves?

Training increases the CRPs' value and affects their level of responsibilities, the types of studies and the ways they are involved in the study. Within the first two years of employment in SickKids, CRAs, if they haven't done so already, will be required to become Certification in Clinical Research Professional (CCRP) accredited to maintain their position. Training should increase with level and experience and CRAs are given training in monitoring, maintaining regulatory documents, and writing informed consent.

They could also be sent to project management workshops, so they can take on the Sponsor responsibility aspects of the study, as well as leadership training programs within the hospital.

Specifically with your active involvement in research, and as a SoCRA board member, how do you envision your role as a Clinical Research Professional (CRP) is impacting society?

In the broadest sense, I'm impacting society by protecting and making a difference in patients' health. Any advances in clinical research cannot be done as part of day-to-day clinical care, and has to be done by a step-by-step business plan approach.

I feel amazing, that my career has an impact on health outcomes and changes in standard practice. In 30 years, there has never been a day where I have not wanted to go to work. I have loved my career that much and have been so engaged in it. I hope my passion for clinical research shines through.

How do you think the Certification Program for Clinical Research Professionals by SoCRA can help to improve the standards and quality of clinical research and trials conducted in institutions?

I feel very strongly about that. Having the Certification Program for Clinical Research Professional (CCRP), is the only accreditation for Clinical Research Professionals. CCRP sets a standard, of the accepted level of knowledge regarding the regulatory requirements, educational, and experience by which clinical research professionals will be recognized by the medical research community.

Certification of CRPs is the one thing in my whole career that I have been a cheerleader for, because what we do is so important. It is beyond me why it hasn't taken off faster, and it is not more worldwide. If we are going to take this profession seriously, I look forward to the day when it is mandatory, because patient safety is at stake.

More information regarding the Certification Program for Clinical Research Professionals through SoCRA (www.socra.org) or ACRP (www.acrpnet.org) can be found at their websites.

References:

1. SoCRA Website: www.socra.org/html/certific.htm
2. International Conference for Harmonisation (ICH) E6
3. Steneck, N.H. *Introduction to the Responsible Conduct of Research*. Department of Health and Human Services USA, Office of Research Integrity. Revised Edition August 2007





SoCRA C.C.R.P Certification Examinations concluded successfully on 8 March 2012!

SoCRA – The Society of Clinical Research Associates – is one of the global leaders supporting the professional development of clinical research associates internationally. It conducts and issues the Certification in Clinical Research Professional (CCRP) for research professionals who are able to demonstrate levels of high competency and knowledge to support and enable proper research administration.

On March 7 and 8, 2012, the NHG Research and Development Office (RDO) hosted the 1st Singapore SoCRA CRP Certification, Preparation, and Review Course as well as the 2nd Singapore CCRP examination at Grand Copthorne Waterfront Hotel, Singapore. The proctor and lecturer is Ms Susan Devine, Chair of the Children's Oncology Group (COG) Clinical Research Associates (CRA) Discipline and member of the COG Executive Committee.

She is also a member of the American Society of Clinical Oncology as well as a SoCRA Board member.

A total of 21 candidates (9 NHG, 6 Partner Institutions, 3 Private Organizations, 3 Overseas Institutions) took part in the CRP Certification, Preparation, and Review Course and 24 candidates (8 NHG, 6 Partner Institutions, 3 Private Organizations, 7 Overseas Institutions) took part in the CCRP examination.

In addition to proctoring the CCRP examination and CRP Certification, Preparation, and Review Course, Ms Devine also presented at the 19th Clinical Research Coordinator Society Forum at Grand Copthorne Waterfront Hotel on March 09, 2012.

The topic touched on is “Responsibilities & Challenges of the Clinical Research Professional – Investigator’s Delegated Responsibilities At The Site”. There were insights shared on Responsible Conduct of Research and the delegation of roles for the research nurses/ coordinators. This event attracted clinical research professionals as well as research students, with an oversubscription of more than 150 participants. Find out more about this forum on page 24.



Participants with Ms Devine at the SoCRA CRP Certification Preparation and Review Course



Introducing the Resources Page

Yeo Kian Wah
NHG Research & Development Office

There is a little but easily overlooked link at the bottom of each webpage at research.nhg.com.sg. The “Resources” link located at the bottom left-hand corner of NHG’s research portal (www.research.nhg.com.sg).

So what is this Resources link all about? Well, for a start, if you are brand new to the whole research enterprise, you can download the NHG Investigators’ Manual - All That An Investigator Needs To Know from this page.

In addition, the Resources page contains all the standard document templates (such as the Study Protocol document and Informed Consent Form) that any researcher will need for writing up a research protocol. It also contains the Research Online Administration and Management (ROAM) guidebooks which will help researchers to navigate and use the ROAM system for creating submissions to the DSRB.



The NHG Research Standard Operating Procedures (SOPs) are available (if you have Intranet access) for downloading too. These are the SOPs that all NHG research-related activities must abide by.

Last but not least, the resources page also contains the informative newsletters such as the Catalyst, Qualité and the ever popular series Chicken Soup for the Busy Coordinator.

So have a look the next time you are at our website and take advantage of this goldmine of information.

Responsible Conduct of Research (RCR) – Human Subject Protection

In the previous issue of Catalyst, we introduced the 8 components of Responsible Conduct of Research (RCR) and elaborated on the 1st component - Research Misconduct. This issue, we look at the 2nd component of RCR, the Protection of Human Subjects.

The society has benefited from research involving the use of human subjects in numerous ways including the advancement and development of medical procedures and technologies, new drugs and to the comprehension of how researchers analyse and act. However, these can also and has imposed unacceptable risks on research subjects.

Therefore, all individuals involved in human subject research have the onus to ensure that the rights, safety and the well-being of research subjects are adhered to by complying with ethical boards regulations as well as any applicable regulatory regulation and policies related to the protection of human subject.

The Nuremberg Code, the Declaration of Helsinki, the National Research Act and the Belmont Report provide

international standards for the protection of human subjects’ safety in clinical research.

Here are some areas one can question to help ensure that subjects are protected:

- Is the study design scientifically and ethically sound?
- Are processes in place to ensure that subjects are informed and are able to exercise their rights?
- If mechanisms are in place to ensure subjects’ safety during participation?
- If safeguards are in place to ensure the well-being of the subjects?
- If safeguards are in place to ensure that the vulnerable research participants are duly in place?
 - Pregnant women, fetuses, and neonates;
 - Children;

- Prisoners;
- Cognitively impaired persons
- Others (e.g. economically or educationally disadvantaged)
- Has the research application received approval from the ethics board and, if applicable, from the regulatory authority?
- Has informed consent been thoroughly and carefully explained to the subject and or if applicable, Legally Acceptable Representative?
- Has consent has been obtained prior recruiting and carrying out research procedures on the human subject?

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

Knowing Our Healthcare Leaders

Interview

Dr Stephen Teoh
Head, Research
Consultant, Uveitis & Vitreoretina Services
National Healthcare Group Eye Institute

What are your thoughts on the current state of collaborative research in your institution?

The National Healthcare Group (NHG) is well known for its cutting edge technology and its pool of high quality clinicians who look after a large patient population with simple to complex diseases. A lot has transformed over the last few years. We have seen an increase in emphasis on research especially collaborative research both internally as well as with external groups- Nanyang Technological University (NTU), A*STAR, pharmaceutical companies, foreign academic institutions etc. This is in line with building NHG into a world-class institution especially in the light of the upcoming Lee Kong Chian- School of Medicine, a joint school between Imperial College of London and NTU. Our challenge is to build on our current momentum and to explore new initiatives in collaborative research and to further establish a core faculty of dedicated clinician-scientists and scientists who can facilitate and bridge the links from 'bench to bedside'.

At the NHG Eye Institute, the Research Unit is a relative fledgling. Set up by Prof Lim Tock Han, and now under our current Head of Department, Dr Wong Hon Tym, and supported by a great team including an excellent Research Manager, Ms Priti Minhas, Research assistants and biostatistician, we have managed to set up an infrastructure that encourages and supports collaboration amongst various local institutions including SERI, NTU, CDC, A*Star and various pharmaceutical research. Although we are still new to the scene of collaborative research, we have taken the first steps in our goal to become the Research Centre we aspire to.



Is there a simple analogy that you would use to describe the "As Is" and "To Be" state of your research in your institution?

The current state of research could be compared to driving a Toyota Camry. It is a good drive, reliable and has good performance and good quality. However we should be striving to be a Lexus 460 - smooth, powerful and top-notch technology!

At the NHG Eye Institute, we definitely have lots of room for expansion and to improve on our efficiency and upgrade our capabilities. But with good senior leadership, coupled with comprehensive policies, infrastructure and incentives, we are getting there, slowly but surely.

What do you think are the qualities of your institution that allows it to catalyse collaborative research?

The most important qualities are its cohort of high-quality, motivated clinicians with a depth of experience in their field. Within NHG, there is access to a wide range of medical specialties with clinicians who have been encouraged to train with various worldwide institutions during their Health Manpower Development Programme (HMDP). In their training, openness to research possibilities is put at a high value.

The leaders in NHG realise the importance of diversity- a key step in generating discussion and cultivating innovation. It is also crucial that

the leaders and various Heads of Department work together to facilitate these research collaboration efforts and the ongoing challenge is to sustain these high-level collaborations.

I believe good inter-personal communication and high quality communication systems are crucial elements to good research collaborations.

Could you share an example of a piece of collaborative research that you are involved in and how it has benefited the various stakeholders?

In the Dengue epidemic in 2004, we saw a large number of patients with retinal involvement following Dengue Fever. This was unusual and rarely reported. Working with the CDC and National Environmental Agency (NEA), we organised a small workgroup within a short period of time that looked at these patients.

This allowed us to characterise the disease patterns and was subsequently the first to report the consistent disease course and pattern of this eye condition in a journal published by the Centres for Disease Control and Prevention (CDC), Atlanta.

The information helped ophthalmologists and infectious disease physicians recognise how Dengue can affect the eye, and more importantly how doctors can counsel and reassure patients on the course of this ocular disease.



On a lighter note, what do you like most about your job?

I am a clinician who was given the opportunity to specialise in both vitreoretina and uveitis, ocular immunology and inflammation, a combination that allows a good juggle of both surgical and medical aspects of ophthalmology and medicine. It also provides the knowledge for both clinical and some basic science research.

Working as part of a healthcare and hospital system that is patient-centered, and in a department that encourages education and research also helps add variety and colour to my job scope, and allows me to learn new things and expand beyond the clinic into various different roles besides being a doctor.

My job is never without a challenge and that is what I love about it. Furthermore, working with a great team gives a lot of satisfaction.

How do you handle the tight demands of your schedule and yet find time for your family?

Each day has its own challenges and is very demanding. So self-discipline and giving priority to time with family and friends is very important. Finding the balance between work and home is never easy, and I tend to allow work to get the better of me at many a time. I do a lot of work from home and work best at night, usually after dinner.

I always carry a notebook so that whenever I have an idea or thought that I think will be helpful for work I can pen it down. I dislike procrastination and likewise, when given a task, I dislike sitting on it.

On weekends though, I try to put family and friends first and a good meal out with them is very relaxing.

What do you like to do in your spare time? Do you have any hobbies?

Most days I keep to a regular gym and exercise routine. It helps to clear my mind and prevents lethargy after a long day's work, apart from battling an expanding waistline! When time permits, I do the occasional round of 'social' golf. I also enjoy travelling but due to tight work schedules, it is difficult to get a long break. Sometimes I take a few days off after a conference to tour the city and around its countryside enjoying the scenery.

In the last few years, I have been going to Vietnam as an ophthalmology instructor in the Harvard Medical School AIDS Initiative in Vietnam (HAIVN). This has allowed me to explore Vietnam and its lovely cities and great culture.

Does your personality and love for your hobbies help in making decisions in your research work?

I have a fairly obsessive personality. I bring a sense of urgency to my work and try to develop a strong mental and physical self-discipline. I have a love for adventure and this might contribute to a sense of experimenting and an enquiring mind with a high level of energy required in research.

I have always encouraged residents physicians to pursue their research interests. I believe that research, like time, does not wait for anyone, so I often advise them that if they are interested in any particular aspect, then - to pick a quote from a famous SciFi character - "Make it so!"



Dr Teoh at HAIVN in Vietnam



DSRB Domain F – Population Health Research

The NHG Office of Human Research Protection Program (OHRPP) will be launching a new Ethics Review Board – Domain Specific Review Board (DSRB) Domain F by Q2, FY2012 - to review Population Health research.

Population Health research involves the study of health outcomes of a group of individuals, including the distribution (e.g. due to race, socioeconomic, gender) of the outcomes within the group. Research that meets the definition of Population Health could now be submitted using a specially designed online Population Health DSRB Application Form through the NHG ROAM portal.

(www.research.nhg.com.sg/sop/process/ROMP/Admin_Intranet_Login)

With the ageing population and the focus shift towards to public health, OHRPP has been seeing an increasing number of study applications involving population health research and more such studies are expected with the setting up of the National University

of Singapore (NUS) Saw Swee Hock School of Public Health.

This propelled the creation of Domain F as the framework for reviewing Population Health research is distinctively different from biomedical research. Often, the biomedical Institutional Review Boards (IRBs) are subjected to a multitude of regulatory obligations for clinical trials which may be irrelevant for Population Health research.

Population Health studies are in general, broad and extensive as the subjects involved in research are not confined to hospitalized patients or the patient pool from healthcare providers, but may also involve a healthy general population.

The types of risks that subjects maybe exposed to, are also often not from the biological perspective but more of financial, mental and/or psycho-social nature. In addition, the risks in Population Health research are often

not only confined to individuals, but extended to communities as well. Thus, the taking of informed consent from participants should not be restricted to individuals, but that of the community consent as a whole should be considered. All these make the identification of risk and the balancing of risk over benefit complex and overwhelming.

In an effort to continuously enhance the overall standards, performance and effectiveness of DSRB, OHRPP recognises the increasing need for a separate Ethics Review Board operated upon distinct policies and procedures to review Population Health research for the thorough and timely review of studies of this nature, ensuring ethical and sound research and at the same time ensuring the protection of human research subjects.

For more information on DSRB Domain F, please contact us at ohrpp@nhg.com.sg or 64713266.

GCP Teasers

NHG's Singapore Guideline for Good Clinical Practice (SG-GCP) training course, held thrice a year, aims to equip participants with the basic knowledge of Singapore's standard operating procedures needed for clinical trials. Let's test your knowledge on SGGCP:

Question 1: In accordance to the GCP guidelines which of the following information is not part of the informed consent discussion.

- a) The approximate number of subjects involved in the trial
- b) The eligible criteria of the subject
- c) The purpose of the trial
- d) The anticipated expenses, if any, to the subject for participating in the trial

Question 2: Complete the sentence from ICH GCP: The investigator should ensure that investigational products are used

- a) Only in accordance with the approved protocol
- b) Only in accordance to investigator's discretion
- c) Only for the approved indication
- d) Only in the institution conducting the clinical trial for trial and non trial patients

Question 3: Who does ICH GCP say should inform the subject about the trial?

- a) The investigator
- b) A member of the investigational site staff
- c) The investigator or a person designated by the investigator
- d) The sponsor

Question 4. An investigator decided to amend the risks section of the informed consent form to increase understanding by prospective subjects to be enrolled in a clinical trial. Which of the following statement is true?

- a) The investigator should only seek IRB approval for the revised informed consent form
- b) The investigator can proceed to use the revised informed consent form without seeking IRB and HSA approvals

- c) The investigator should seek IRB and HSA approvals for the revised informed consent forms
- d) The investigator should make the necessary amendments on the informed consent form whilst explaining it to the subject

Question 5. Which of the following may not constitute a source of legal rules or obligations governing conduct of a clinical trial?

- a) SGGCP
- b) Association of the British Pharmaceutical Industry guidelines
- c) Clinical Trial Agreement
- d) Medicines Clinical Trial Regulations

Answers: 1. (b) 2. (a) 3. (c) 4. (c) 5. (b)



Proper Conduct of Research

Retaining & Managing Subjects Under Follow-Up

What are the strategies for retaining and maintaining research subjects during the enrollment or follow-up period? The researcher or their delegated study team member may face the challenge of losing subjects due to various reasons during the course of the study, especially for studies spanning across a number of years.

The following are some tips for preventing loss of enrolled subjects during the follow-up period.

Tips for Subject Follow-up

- Ensure that the subjects know what is expected of them;
- Ensure that the study experience is good ;
- Keep the subject's interest going;
- Identify the risk of subject leaving the study;
- Call the subject to remind about the visit;
- Update contact information at every visit;
- Ask patients if they have mobile phones or if they prefer communicating via other means (e.g. e-mail) (Some patients prefer the latter);

- Find out if the subjects expect to move in the next 6 months;
- Phone the patient at different times of the day and on weekends; and
- Check clinic charts, hospital records, and family physician, as per your institutional policy, to see when the patient was seen last.

Managing & Documenting Loss to Follow-up

Loss to follow-up does not necessarily mean that the subjects do not want to continue in the study but is unable to attend the scheduled visits due to unforeseen circumstances.

In this event, the researcher should contact the subject to complete a termination or final visit.

Attempts to contact subjects should be documented and letters or emails sent kept. The Subject Visit Schedule Log should also be updated up till the last visit. The subject's status and end date of participation should be recorded in the subjects medical records.

The Role of a Clinical Research Coordinator (CRC)

The Clinical Research Coordinator (CRC) plays an important role in supporting the Investigator in the subject follow-up process.

Learn more about Subject Follow-up from experienced research coordinator / managers in the Proper Conduct of Research – Basic II (PC102) module.

The National Healthcare Group's (NHG) Proper Conduct of Research (PCR) training courses aim to ensure that clinical research team members are able to understand the key principles of PCR Standard Operating Procedures (SOPs) and apply their knowledge in their work.

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

References:

- *NHG PCR Standard Operating Procedures 501-Co3 Subject Management During Study* (www.research.nhg.com.sg > Resources > Research SOPs)
- *Basic PCR (PC102 module) Subject Follow-Up*
- *Clinical Trials Networks Best Practices* (www.ctnbestpractices.org/resources/study-patient-management/subject-follow-up/followuptips.doc/view)

PCR Teasers

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

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

Question 1: A Clinical Trial involves 10 visits. Subject will be reimbursed \$50 per visit. The Clinical Research Coordinator (CRC) informed subjects at Visit 1 that she would pay the subjects \$500 at the 10th Visit. Is this acceptable? Why?

- Yes, since it is easier for the CRC to keep track of the payments made to the subjects.
- Yes, since the subject would prefer it this way.

- No, since this may cause undue influence on the subject to complete the study.
- No, since the CRC may not have a lump sum available at the end of the study to pay all the subjects.

Question 2: Which of the following essential documents is important for subject retention?

- Subject Visit Schedule Log
- Subject Identification Log

- Subject Screening Log
- Subject Enrollment Log

Question 3: Which one of the following elements does not need to be captured on a Subject Visit Schedule Log?

- Subject Name
- Expected Visit Date
- Actual Visit Date
- Subject ID and Initials

Did you get them right?

Answers: 1. (c) 2. (a) 3. (d)

Useful Websites for Researchers

Asia

Asian Bioethics Association
www.eubios.info

The Eubios Ethics Institute is a non-profit group, based in Japan, that aims to stimulate the international discussion of ethical issues, and how we may use technology in ways consistent with “good life” (eu-bios). It aims at an integrated and cross-cultural approach to bioethics, and at building up an international network.

Australia

Australasian Association of Bioethics and Health Law
www.aabhl.org

Formed in 1991, the association aims to:

- Promote the study of bioethics in Australasia.
- Provide a public forum for debate and discussion of bioethics.
- Promote awareness of bioethics and bioethical issues in the community, among all those involved in health care and related disciplines.

Centre of Human Bioethics, Monash University
www.arts.monash.edu.au/bioethics/index.php

The aims of the Centre for Human Bioethics are:

- To carry out research on issues in human bioethics and to promote study of the ethical, social and legal problems arising out of medical and biological research.
- To provide an advisory and resource centre for government, professional, educational and community groups.
- To stimulate the development of educational programs in human bioethics for professionals and the public. The Centre has carried out research projects on many different topics.

Canada

University of Toronto Joint Centre for Bioethics
www.jointcentreforbioethics.ca

This Centre is a partnership between the University of Toronto and affiliated hospitals. It studies important ethical, health-related topics through research and clinical activities. It has published papers on human rights in the biotechnology era; xenotransplantation and cloning; stem cell transplantation; and genetic testing.

International Sites

World Health Organization (WHO)
www.who.int/en/

WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

Helpful Resources

Are you currently running or planning to start a clinical trial that involves the use of medicinal product that requires a Clinical Trial Certificate (CTC) ?

If you ever had any questions pertaining to the application and requirement of the regulations, this might be a good place to find some commonly asked questions before you start hounding those around you or calling the Health Sciences Authority (HSA’s) desk.

The questions are categorised into 10 sections based on their topic relation, namely Regulatory Requirements For Clinical Trials, Clinical Trial Certificate (CTC), Other Regulatory Requirements And Guidance For Clinical Trials , Principal Investigator, Sponsor, Informed Consent Form and Investigational Products (IP) and Labelling, Biological Samples and Pharmacovigilance.

This website is a useful reference to HSA’s stand, view points and recommendations especially towards certain areas in the clinical trial conduct where the existing guidelines are not explicitly clear or mentioned in the Singapore Guideline for Good Clinical Practice (SGGCP) or in the Medicine (Clinical Trials) Regulations. With the ongoing inspection by HSA, it will be wise to be familiar with the regulatory requirements and how it is being applied in the clinical trials you are conducting. However, if in any doubt, researchers should contact HSA directly for any queries that they may have

pertaining to their trial at any stage and prior to implementation.

HSA’s FAQ section can be found at:

www.hsa.gov.sg (Home > Health Products Regulation > Clinical Trials > FAQs)

OR

www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/faqs.html





Asia Pacific Research Ethics Conference (APREC) 2012

APREC 2012 – “Bridging Cultures, Enhancing Research”, held at the Grand Copthorne Waterfront Hotel Singapore from 7 to 9 March was a huge success for NHG.

Working in collaboration with Public Responsibility in Medicine & Research (PRIM&R), our partner from the United States, the conference saw a turnout of 260 international delegates, including 85 distinguished speakers from Asia, the United Kingdom, Saudi Arabia, Australia and USA.

Topics discussed included pertinent issues faced by the various Institutional Review Boards (IRBs); ethical and legal considerations in human research; and overcoming challenges of international clinical trials.

A/Prof Chin Jing Jih, Divisional Chairman (Integrative and Community Care) & Senior Consultant, Tan Tock Seng Hospital is Chairman of the APREC 2012 Organising Committee.



Professor Chee Yam Cheng, Chief Executive Officer, National Healthcare Group (first from left) with APREC 2012 Keynote Speakers at the Opening Ceremony of APREC 2012



Associate Professor Chin Jing Jih – APREC 2012, Organising Committee Chairman delivering citation for Keynote Speaker - Dr Ezekiel J. Emanuel



Opening Keynote – Dr Ezekiel J. Emanuel, Diane v.S.Levy and Robert M. Levy University Professor, Vice Provost for Global Initiatives, Chair, Medical Ethics and Health Policy, University of Pennsylvania, delivering his Keynote speech



Opening Keynote – Dr Ezekiel J. Emanuel, Diane v.S.Levy and Robert M. Levy University Professor, Vice Provost for Global Initiatives, Chair, Medical Ethics and Health Policy, University of Pennsylvania, receiving his token of appreciation from Professor Chee Yam Cheng, Chief Executive Officer, National Healthcare Group



Distinguished speakers and APREC 2012 Organising Committee at networking lunch



Ribbon distributions at APREC 2012



APREC 2012's exhibition at Grand Copthorne Waterfront Hotel's foyer



Poster Display at APREC 2012



Delegates planning out their activities for the day at APREC 2012



Participants had opportunities to seek the expertise of distinguished speakers at Breakout sessions



Closing Keynote Speaker – Professor Alistair V. Campbell, Director, Centre of Biomedical Ethics, Yong Loo Ling School of Medicine, National University of Singapore, Chen Su Lan Centennial Chair in Medical Ethics, National University of Singapore, Member, Biomedical Advisory Committee (BAC), delivering his Keynote lecture



Hardworking Secretariat Committee of APREC 2012



Happy delegates at APREC 2012



Keynote Speaker, Professor Toshiaki A. Furukawa delivering his lecture titled, Research Ethics Poser: Where is the Truth in the Sea of Information?



Keynote Speaker, Dr. Johan P.E. Karlberg delivering his lecture titled, Research Ethics Falling Behind Globalisation of Clinical Research

19th Clinical Research Coordinator Society (CRCS) Forum 2012

The 19th Clinical Research Coordinator Society (CRCS) Forum was held at Grand Copthorne Waterfront Hotel on the 9th March 2012, in conjunction with the 2-day Asia Pacific Research Ethics Conference organised by National Healthcare Group.

This 2-hour long forum drew a huge turnout of more than 150 participants. The invited speaker, Ms Susan Devine (*Senior Manager, Clinical Trial Support Unit Hospital for Sick Children in Toronto*) spoke on the topic "Investigator's Delegated Responsibilities At The Site", focusing on how an investigator should adhere to responsibilities and tasks through various means to ensure patient safety and data integrity.

Using an oncology trial as an example, she further illustrate her points with other specialties, which attracted a wide range of participants. Many burning questions were raised during the intriguing panel discussion which lasted for 45 minutes.

Ms Clare Tan (*Associate Manager, PPD (Pharmaceutical Product Development, INC)*), chaired this panel discussion. Apart from Ms Susan Devine, the other panelists included Ms Sumitra Sachidanandan (*Compliance Inspector, Health Sciences Authority*), A/Professor Sim Kang (*Principal Investigator, Institute of Mental Health*), Ms Yew Lay Hwa (*Senior Manager, Clinical Trial Research Unit at Changi General Hospital*) and

Ms Ho Wai Han (*Clinical Manager, PPD*). The topics discussed during the panel discussion were Informed Consent Process, Subject Eligibility and Patient Safety.

We wish to thank all participants of this forum for their support and look forward to seeing you at the upcoming forum in the later half of the year!



The panel discussion was held during the CRCS Forum

NHG Research Leadership & Management Forum

In conjunction with the Asia Pacific Research Ethics Conference (APREC) 2012, the 1st NHG Research Leadership & Management Forum was held at the Grand Copthorne Waterfront Hotel on 9th March 2012.

In accordance to APREC 2012, the theme for this Forum was "Research & Ethics - How Do Leaders Feel?"

This inaugural NHG Research Leadership & Management Forum is an extension of the former NHG Research Admin Roundtable.

The closed-door executive event serves as a platform for key thought-leaders from the local healthcare, research, clinical sciences and academic community to share and discuss imperative issues and strategic opinions for the local research industry.

By invitations-only, the event was attended by many guests consisting of Chief Executive Officers, managing directors, directors, managers, and researchers from local healthcare, research, academic institutions and pharmaceutical companies.



Prof Stephen Smith, Vice-President (Research), Nanyang Technological University and Founding Dean, Lee Kong Chian School of Medicine was invited to speak about the perspectives from a Research-Intensive Academic Institution.



A/Prof Lim Tock Han, Assistant CEO (Research & Education), National Healthcare Group, graced the event with an opening address.



While Dr Nazrin Azli, Director and Lead, Global Trial Operations, South East Asia Sub Region, Merck & Co. Inc. (MSD) spoke on the perspectives from the Pharmaceutical Industry.

"Both speakers gave insightful and valuable information from their points of view which in turn won the applause of many."

NHG FY2012 Grant Results

The Small Innovative Grant I (SIG I) is a short-term grant designed to support clinical research that answer specific, targeted research questions or to perform pilot or feasibility studies. SIG I is designed to support small start-up exploratory studies that may provide preliminary findings for larger research proposals.

In the Clinician Leadership in Research (CLR) programme, the Principal Investigator (PI) would be supported to attend a minimum 56 hours of modular training over the 2 year programme. These courses will be taught by the CLR Teaching Faculty and professionals.

In November 2011 last year, the FY2012 Small Innovative Grant I (SIG I) and Clinical Research Leadership in Research (CLR) Grant Calls were launched. Our heartiest congratulations to the FY2012 SIG I and CLR awardees below:

Small Innovative Grant I (SIG I) Awardees

S/N	Project Title	Principal Investigator	Institution	Department
1	Meticillin-resistant staphylococcus aureus (MRSA) screening at hospital admission: the cost effectiveness of universal screening vs. screening only high risk patients	Dr Sun Yan	NHG HQ	Health Services and Outcomes Research
2	Patterns of mood and anxiety disorders in parents of clinically referred children: Laying the foundation for a family-based approach to mental health	Dr Sharon Cohan Sung	IMH	Child and Adolescent Psychiatry
3	Longitudinal brain abnormalities and their relationship to outcome after first episode mania: a prospective structural magnetic resonance and diffusion tensor imaging study	A/Prof Sim Kang	IMH	General Psychiatry
4	Linking the dots: Elucidating Glutamate related genetic effects on brain white matter integrity in schizophrenia and bipolar disorder	A/Prof Sim Kang	IMH	General Psychiatry
5	The role of endothelial progenitor and circulating endothelial cells in cardiovascular risk of patients with sub clinical hyperthyroidism; randomised placebo controlled study	Dr Shaikh Abdul Kader Kamaldeen Abdul Shakoor	TTSH	Endocrinology
6	A multi-centre, randomized control trial piloting the adjunctive use of Nintendo WiiFit Exercise program for the rehabilitation of geriatric patients with surgically treated hip fractures	Dr Tjan Soon Yin	TTSH	Rehabilitation Medicine
7	Distinguishing active from latent tuberculosis infection using CD4 T cell intracellular cytokine staining and flow cytometry	Dr Timothy Barkham	TTSH	Laboratory Medicine
8	Comparison of the durability of immunological responses against influenza in healthcare staff given standard trivalent inactivated vaccine (TIV) and live attenuated influenza vaccine (LAIV)	Dr Mark Chen	TTSH	Infectious Disease
9	Predicting Alzheimer's Dementia Progression: Development of initial multicariate models of clinical decline for subsequent validation	Dr Mark Chan Peng Chew	TTSH	Geriatric Medicine



NHG FY2012 CLR Awardees

Clinician Leadership in Research (CLR) Awardees

S/N	Project Title	Principal Investigator	Institution	Department
1	Proteinuria as a predictive marker of dengue haemorrhagic fever	Dr Gan Chih Hao Victor	MOHH / Tan Tock Seng Hospital	Clinical Epidemiology
2	Predictive Modeling for Chronic Kidney Disease Progression	Dr Ang Yee Gary	National Healthcare Group	Health Services and Outcomes Research

To find out more about NHG Intramural Grants, please visit www.research.nhg.com.sg (Grants & Programmes > NHG Intramural Support).

About Dr Gary Ang Yee

"I am glad for this opportunity to be awarded into the Clinician Leadership in Research programme. The programme is rigorous and structured and would help me clarify my research aims, objectives, and work on the relevancy of the research in this practical world. The scope of Health Services Research is wide and I hope that the CLR will help me have a firmer idea of which aspects of HSR to pursue as a career.

Currently, I am doing my advanced specialty training in Public Health at both NHG Health Services and Outcomes Research and the NHG Polyclinic Clinical Services. My interest in Health Services Research first started during my 2 year part time Masters of Public Health (MPH) course in National University of Singapore.

About Dr Victor Gan

"My interest in translational research started early with a project on cloning of CD38 in junior college leading to the award of the National Science and Technology Board Merit Award and scholarship, prior to acceptance into University College London for medical studies.

I continued to be active in research, working on Schwann-cell directed embryonic stem cell differentiation in my second year of medical school under Prof Rhona Mirsky, and on characterization of BPAG-1, a cytoskeletal protein at the Department of Pathology in Columbia University, New York City in a summer attachment as a research fellow under Prof Ronald Liem, published in the Journal of Cell Biology in 2001.

After returning to Singapore, I continued to be closely involved with research under the STOP

At one of the modules, I was exposed to researchers from diverse fields working on Health Services Research. As part of my MPH, I completed a practicum on the rate of progression of subjects with impaired fasting glycaemia to Type 2 Diabetes Mellitus using the NHG Diabetes Registry.

This study has been accepted for publication by Journal of Diabetes and an oral presentation based on the study at the 45th Annual Singapore Malaysia Congress of Medicine 2011 has won merit award. This had increased my interest in pursuing Health Services Research as a career.

Dengue Translational Clinical Research Programme at CDC, TTSH, being a co-investigator on several studies, and involved in setting up new studies. I am convinced of the necessity of clinicians to engage in research in order to improve health outcomes both as an individual, and in particular with my increasing involvement in infectious disease epidemiology, at a population level. I hope my broad experience in laboratory based, clinical and epidemiological research will allow me to bridge the gap and promote multidisciplinary efforts so critical for progress.

Being part of CLR I hope will provide structured training, a career path, as well as interaction with like-minded clinician researchers, during which I hope to share my own research experiences here and overseas with my colleagues.



At the end of the day, I hope to become a Health Services researcher so that I can help contribute to this exciting field of HSR in Singapore and bridge the distance between evidence and implementation"



Ultimately, the promotion of a conducive environment for research by clinicians is the only way to maintain our health service provision at a high level, engage clinician leaders and develop the biomedical community in Singapore. Being a part of this as a participant in the CLR would be my great privilege."



Upcoming Grants calls in Singapore

1. National Medical Research Council (NMRC) Grants

NMRC aims to establish a comprehensive and transparent set of grant schemes that support individuals and targeted programme areas. The grant schemes are designed for translational and clinical investigators across all of Singapore who will have the opportunity to participate in multiple ways in this coordinated grant framework.

The following grants will be opened on the first working day of May 2012. For more details on the submission requirements and deadline, visit NMRC's website at www.nmrc.gov.sg.

a) CS Individual Research Grant (CS-IRG)

Eligibility

Each CS-IRG application must be led by a Clinical PI. The Clinical PI should be clinically qualified (i.e. with MD/MBBS/BDS) and preferably with post-graduate clinical training and experience. For proposals involving patients, the clinical PI or co-I should be SMC registered; or should be able to demonstrate ability to access patients through SMC registered collaborators.

Funding

The CS-IRG will provide a funding quantum of up to S\$1.5M per project for 3 years with additional 20% indirect costs provided to the host institution of the lead PI.

b) CS-IRG New Investigator Grant (CS-IRG-NIG)

Eligibility

This is a subcategory of the CS-IRG to cater for new clinical investigators. Applicants with substantial research experience will not be accepted under this category. Each CS-IRG-NIG application must be led by a Clinical PI. The Clinical PI should be clinically qualified (i.e. with MD/MBBS/BDS) and preferably with post-graduate clinical training and experience. For proposals involving patients, the clinical PI or co-I should be SMC registered; or should be able to demonstrate ability to access patients through SMC registered collaborators.

Funding

The CS-IRG-NIG will provide a funding quantum of up to S\$200,000 per project for 2 years with additional 20% indirect costs provided to the host institution of the lead PI.

c) Transition Award (TA)

Eligibility

The Transition Award is a new award launched by NMRC in 2011 to provide funding support for budding clinician scientists. The TA is open for highly promising applicants who are clinicians that have received in-depth scientific training or at least 2 years of post-doctoral intensive research experience, in relevant local or overseas universities, research institutes, and centers.

Funding

The TA provides funding support of up to 3 years, for mentored research project with salary and grant funding. Funding support is capped at \$375,000 for up to 3 years, with 20% indirect costs and is non extendable.

d) Clinician Scientist Award (CSA)

Eligibility

The Clinician Scientist Award (CSA) has two levels of award, namely the Investigator Category (INV) and Senior Investigator Category (SI) for applicants with different levels of research experiences.

Applicants must be clinically qualified PIs and preferably with post-graduate clinical training and experience. PhD-holders or equivalent such as biostatisticians, nurses, pharmacists, psychologists and allied health professionals who have active interactions with patients or with clinically relevant research are welcome to apply.

Funding

For the INV Category, the award includes 3 years' salary, grant support of up to \$225K per year for 3 years with 20% overhead costs. For the SI Category, the award includes 5 years' salary, grant support up to \$350K per year for 5 years with 20% overhead costs.

2. MOH Health Services Research Competitive Research Grant (MOH-HSR CRG)

The Health Services Research Competitive Research Grant is a MOH research grant established in 2009. This HSR CRG aims to promote the conduct of HSR and enable the translation of HSR findings into policy and practice.

The HSR CRG grant will be opened on the first working day of May 2012. For more details on the submission requirements and deadline, visit MOH's website at www.moh.gov.sg

Eligibility

PI for HSR CRG should possess a minimum academic qualification of PhD and/or MBBS/BDS/PharmD/MD and/or other appropriate Postgraduate Qualification. The PI should hold at least an adjunct position in a local public institution and salaried by the institution, have access to a laboratory to conduct research and reside in Singapore.

Funding

Funding for each HSR CRG application will be capped at a total of S\$200,000 for research proposals under Phase 1 and Phase 2, and capped at a total of S\$1,000,000 for research proposals under Phase 3.



QUALITÉ

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

ISSUE 2012/04

+ PROTOCOL NON-COMPLIANCE DSRB AND SUBJECTS NOT UPDATED OF STUDY CHANGES

The Principal Investigator (PI) was replaced by the Co-Investigator as the initial PI had left the institution.

+ UNDERSTANDING THE DIFFERENCE AND PREPARING FOR MONITORING, AUDIT AND INSPECTION



FREQUENTLY ASKED QUESTIONS (FAQS) ON TRIAL CONDUCT

FAQ: What types of changes constitute a protocol amendment and requires a submission to Domain Specific Review Board (DSRB) and/or Health Sciences Authority (HSA). And which requires only a notification or submission to DSRB?

ANSWER: If the Principal Investigator (PI) anticipates amendment(s)/ changes to a protocol, regardless of its significance - minor, major or administrative, these amendment(s)/ changes should be submitted to DSRB and HSA, if applicable. Protocol Amendments may be necessary to further protect the safety and welfare of the research subjects and to further improve the scientific and research soundness of the protocol. Therefore, DSRB receives and reviews submitted protocol amendments and determines the category of review for the changes that have been made to the approved proposal.

Administrative Amendments such as a change in the address, contacts and correction of typographical and grammatical errors should be submitted to the DSRB for review. An acknowledgment letter by the DSRB will then be sent to the Investigator/ Sponsor. If the study is a HSA approved study, submission of administrative changes is not required. However, proper records of these changes should be maintained in the study site and sponsor files and made available to HSA upon request.

Minor Amendments are determined by DSRB if the changes to the protocol affect the risk-benefit assessment. Changes to the protocol that pose any increase in risk which is not more than minimal risk,

or new procedures added that fit within the categories are eligible for expedited review. The Sponsor and/or PI should contact the HSA if they are unsure if the minor amendment(s) constitute a submission to HSA.

Major Amendments that significantly increase the overall risk or negatively alter the risk-benefit ratio to the subjects of the study will be reviewed at a DSRB Full Board Review meeting (e.g. a major change to the consent document or process that increases the overall risk to the subject involved in the study must be submitted to DSRB). HSA requires the Sponsor and/or PI to submit such major amendments as well as a copy of the amendment document.

The Sponsor and PI need to obtain approval from both DSRB and HSA before the amendment can be enforced.

PIs and Sponsors should check with DSRB and HSA for further clarifications if unsure about their protocol amendment submission and/or procedures.

References:

- SGGCP 6 Clinical Trial Protocol and Protocol Amendment(s)*
- NHG DSRB SOP 201-C11 & NHG Investigator Manual*
- Health Sciences Authority Frequently Asked Questions*
- Good Clinical Practice: A Question & Answer Reference Guide May 2011*

UNDERSTANDING THE DIFFERENCES AND PREPARING FOR MONITORING, AUDIT AND INSPECTION

Well, you may ask, why is there a need to perform all these activities (i.e. Monitoring, Audit and Inspection) when a study has already been approved by the relevant Institutional Review Boards (IRB) or Regulatory Authorities?

Imagine if your loved one was asked to participate in a research study, what type of a mental checklist would you have before encouraging your loved one to participate in it?

- Your loved one is safe and his/her rights are protected
- The data obtained will be of good quality and integrity so that it will not be a waste of his/her effort
- Your loved one is under the protection of the available guidelines and regulatory requirements
- The operations of the study are well planned

These are very similar to the following points:

Purpose of Performing Monitoring, Audit and Inspection

- To safeguard the rights, safety and well-being of subjects participating in research studies;
- To verify the quality and integrity of the research data - to ensure that the data are accurate, complete and verifiable from source documents;

The conduct of the trial is in compliance with the currently approved protocol/amendment(s), applicable Standard Operating Procedures (SOP), SG-GCP, and the applicable regulatory requirement(s). Some of these guidelines and requirements may include the respective institutional SOP and Institutional Review Board (IRB) SOP, SG-GCP, Medicines (Clinical Trial) Regulation, Guidelines for Clinical Trials provided by Health Sciences Authority (HSA) and Proper Conduct of Research SOP provided by National Healthcare Group (NHG).

- To assess whether the systems set up to conduct the research studies are suitably designed, controlled, maintained and documented to fulfill the objectives of the study; and
- To identify areas for quality improvement in conducting research

It may be difficult to ensure all of the above through a study application. Therefore, monitoring, audits and inspections are performed. The monitor/ auditor/inspector may look into all aspects of the research study, including the approval of the study application, subject recruitment methods, informed consent process, management of investigational products, documentation of study-related procedures and safety monitoring.

The Differences of Monitoring, Audit and Inspection

The distinction lies in the responsibilities of different parties and the different frequencies for the conduct of these activities.

MONITORING

Monitoring is carried out periodically and is applicable for all clinical trials. All clinical trials should include adequate provisions for the purpose of monitoring the conduct of a research study. The monitoring plan for a particular research study would depend on the complexity of the research study and the possibility of potential harm to subjects.

For Investigator-Initiated Clinical Trials, the Principal Investigator (PI) is responsible for having a written monitoring plan prior to study initiation. Clinical trials should be monitored regularly by a monitor who is independent of the research team. You may find the Monitoring Plan Template provided by (NHG-RDO) useful in drafting your respective monitoring plan. It can be found on National Healthcare Group – Research & Development Office’s research portal (www.research.nhg.com.sg) (Resources -> Monitoring Plan Template).

For Industry Sponsored Clinical Trials, the PI is responsible for ensuring that the sponsor provides a monitoring plan for the clinical trial.

On the other hand, audits and inspections are 2 forms of quality assurance for clinical research/trials.

AUDITS

Audits are usually carried out on an ad-hoc basis. It can be performed by the institution or the sponsor. Audits, conducted by the NHG Research Quality Management team, apply to all research studies conducted at institutions under the oversight of NHG Domain Specific Review Board (DSRB).

INSPECTIONS

Inspections are also carried out on an ad-hoc basis, but it is usually performed by the regulatory authority (i.e. Health Sciences Authority (HSA) in Singapore). They may be conducted on clinical trials involving medicinal products, where a clinical trial certificate has been issued. GCP Site inspections may be either protocol-specific or systems-oriented. Systems that may be inspected include Investigator site files, informed consent, investigational

products, pharmacovigilance, biological samples, monitoring, data management, biostatistics and final reports.

Preparing for Audits and Inspections

As a principal investigator, you are responsible for ensuring that there is adequate preparation for the audit/inspection, cooperation with the auditor/inspector and appropriate follow-up actions.

You may wish to refer to NHG PCR SOP 501-B10 (Handling Audits) for more guidance on how to prepare for an audit/study review by NHG. Prior to that, you may also find the Investigator File Content Template and the Essential Document checklist, provided by NHG-RDO, useful to ensure all essential documents are in the investigator file.

For more details about the inspections by the HSA, you may refer to Guideline on GCP Compliance Inspection Framework, available on their website.

Helpful tools and resources

1. Proper Conduct of Research Standard Operating Procedures and Templates www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+sops
2. Guideline on GCP Compliance Inspection Framework www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/guidelines/gcp_compliance_inspection.html

Templates available from NHG-RDO (under the PCR SOP link mentioned above)

1. Investigator File Contents Template
2. Essential Documents Checklist
3. Monitoring Plan Template

References:

Singapore Guideline for Good Clinical Practice (SGGCP)
NHG Proper Conduct of Research Standard Operating Procedures
Health Sciences Authority, Guideline on GCP Compliance Inspection Framework

PROTOCOL NON-COMPLIANCE DSRB AND SUBJECTS NOT UPDATED OF STUDY CHANGES

Background

In a recent study, the Principal Investigator (PI) was replaced by the Co-Investigator as the initial PI had left the institution. As the Co-Investigator had been an active member from the start of the study, subject enrolment and other study activities continued without informing the Domain Specific Review Board (DSRB) and research subjects.

In another study, study procedures were not performed due to lack of resources and the PI was in the midst of securing the necessary grant/resources to continue the study. These changes however were not communicated to the DSRB and subjects.

Findings & Implications

The PI had implemented changes to the study without ensuring that prior review and documented approval/

favourable opinion from the DSRB had been obtained. The PI also did not update the information in the Participant Information Sheet/Consent Form provided to the ongoing research subjects enrolled in the study.

By not providing the updated information to the DSRB and research subjects, the PI had compromised on the ethical review and the informed consent process of the study. The changes to the study may affect the subject's willingness to participate or continue participation in the study.

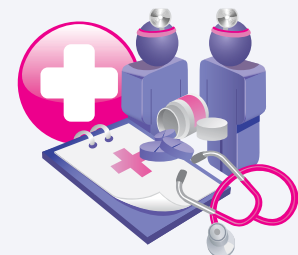
Tips and Recommendations

- It is advisable to always notify the DSRB and Health Sciences Authority (HSA) (if applicable) of changes made to the study. In general, major changes can be done via a protocol amendment, and minor/administrative changes may be made via a notification.

- To avoid making too many changes to the study, the PI may try as much as possible to finalise study details before submitting it for approval. The PI should also be prepared to implement changes only after receiving favorable approval and opinion from DSRB and HSA (when applicable).
- The PI should update the study protocol and Participant Information Sheet/Consent Form and/or create an addendum for research subjects who had given consent previously to document new information that may be relevant to the research subject's consent. Any new information communicated to the research subjects should be documented.

References:

Singapore Guideline for Good Clinical Practice (SGGCP) 4.4.1, 4.5.2, 4.8.2



NHG Research Training Calendar

for April – June 2012

Date	Time	Course Title	Course Category	Course Module	Venue
25 April	09:00 - 16:30	NHG Proper Conduct of Research - Advanced I (PC301) Workshop	Proper Conduct of Research	PC301	
27 April	08:45 - 13:15	Research Governance, Informed Consent and Institutional Review Board (IRB) Workshop	Research Ethics	RE101C	
11 May	14:00 - 17:30	Essential Documents & Subject Recruitment & Follow Up	Research Ethics	RE102C	National University Hospital, Kent Ridge Wing, Level 2, Advanced Surgery Training Centre
17 - 18 May	09:00 - 18:00	Project Management for the Research Team	-	-	
4 June	13:30 - 17:45	Documentation and Audits Workshop	Research Ethics	RE104C	
18 June	09:00 - 13:00	Investigational Products and Safety Reporting Workshop	Research Ethics	RE103C	
11 - 13 July	09:00 - 18:00	Biostatistics Workshop	Research Methodology	RM101C & RM102C	TBC
16 - 17 July	09:00 - 17:30	STATA Workshop			

For registration and full details, please visit www.research.nhg.com.sg (Training & Education > Search for a Course)

Upcoming Conferences in Singapore

Date	Title of Course	Venue
2 May - 5 May	9th Asia Pacific Travel Health Conference	Grand Copthorne Waterfront Hotel
14 May - 16 May	Biostatistics for Research (Advanced Level)	Singapore General Hospital Block 6, Level 1, IT Training Room 1
25 May - 27 May	University Obstetrics & Gynaecology Congress (UOGC) 2012	Marina Mandarin
7 June	Urinary Incontinence	Singapore General Hospital
7 June - 8 June	5th International Singapore Symposium of Immunology	Town Plaza Auditorium, University Town, National University of Singapore
21 June - 24 June	Primer in Paediatric Nephrology for Asia	NUHS Tower Block
13 July - 15 July	19th Asean Federation Cardiology Congress 2012 (AFCC2012)	Raffles City Convention Centre
18 Mar – 21 Mar (2013)	World Stem Cells & Regenerative Medicine Congress 2013	–

