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ACCELERATING **RESEARCH**

A NEWSLETTER FOR THE RESEARCH COMMUNITY IN SINGAPORE

MAY/JUNE 2011

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MEDICAL EDUCATION & RESEARCH

**EXCLUSIVE
INTERVIEW**

Senior Vice Dean
Lee Kong Chian
School of
Medicine



UPCOMING EVENTS

**UPCOMING
GRANT CALLS**



CLINICAL RESEARCH

**SHBC 2010
NURSING AWARD
WINNER**



SPECIAL FEATURE

**KNOWING OUR
HEALTHCARE LEADERS**
Professor Martyn R Partridge

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from the editor-in-chief

Dear Readers,

In this issue, it is our pleasure and honour to bring to you an exclusive interview with Professor Martyn Partridge, Senior Vice-Dean of Lee Kong Chian School of Medicine. Professor Partridge shares with us his views and thoughts on the new medical school, this new era of medical education and how research will be important in the next phase of healthcare environment.

Indeed, research is an important element in the overall learning & improvement process. It is through the constant questioning of the status-quo, coupled with the courage and perseverance to discover answers that medical professionals and organizations can improve and learn.

Also, the NHG Research & Development Office (RDO) will be rolling out the 1st comprehensive online research management portal and system by end June 2011. After 2 years of planning and development, RDO conquered all odds and is now ready to roll out the new paperless system. Indeed a journey commanding great endurance.

As a research support office, RDO constantly challenges the current paradigms and seek new ways to improve. Although our paper processes had been a comfortable one with no critical issues, the online system will further enhance the efficiency of our review processes. This will also bring about more effective research support services to our investigators and research team members.

At the same time, RDO is developing a research mobile platform for our research community. Soon, you will be able to check your project status through your mobile applications, and receive automatic alerts. I take this opportunity to thank the ROAM development team, our Domain Specific Review Board (DSRB) Chairs & members and investigators for your support and patience for making these changes a reality.

Last but not least, I congratulate the editorial team who successfully revamped Catalyst with its fresh new look. I look forward to more positive changes ahead.

Enjoy reading.

Yours Sincerely,
Kin Poo

Your Newsletter Your Comments

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

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

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

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2010 Advancing Ethical Research (AER) Conference – Uniting People, Principles and Practices

SAN DIEGO – The AER conference is an annual event organized and sponsored by the Public Responsibility in Medicine and Research (PRIM&R), which is dedicated to advancing the highest ethical standards in the conduct of research. Last year, the 3-day programme was held on the 6th – 8th of December at the San Diego Convention Centre. Attendees could also register for the one-day pre-conference educational programme that included workshops tailored for a wide range of professionals, including IRB members/staff, institutional officials as well as those in need of ‘refreshers’ in ethics.

PRIM&R’s AER conferences were designed to be a platform to connect all those who work or participate in the fields of human research and to allow the stakeholders to discuss and share their experiences on complex and challenging research issues.

Their commitment was evident in the theme chosen for last year’s AER conference “Uniting People, Principles and Practices”. As a testimony to the popularity and success of the annual event, last year’s conference witnessed an increase of 300 attendees in comparison to the preceding year and attendees came from all 50 states and 30 countries.

The three keynote speakers for the conference were Dr Francis Collins, Director of the National Institutes of Health; Ms Rebecca Skloot, author of *The Immortal Life of Henrietta Lacks*; and Ms Eva Mozes Kor, Auschwitz survivor and founder of the CANDLES Holocaust Museum. They were undoubtedly one of the highlights of the conference as the keynotes were delivered with much charisma and left the audience re-thinking about the principles and policies governing human research ethics.

A notable moment was when an attendee stood up and asked Ms Kor if she had

ever been nominated for the Nobel Peace Prize. Ms Kor had shared her personal story as a Holocaust research subject who had endured the inhumane experiments conducted by the Nazi doctors.

After many years of torment and struggle, she finally found the strength to forgive the doctors who had violated hers and her twin sister’s rights as human beings. The Nuremberg Code is a result of these crimes against Ms Kor and countless others and forms the basis for human subject protections today.

Attendees were also entertained and refreshed each morning when Co-Chairs of the conference organizing committee, Dr Ivor Pritchard and Ms Michele Russell-Einhorn presented their renditions of songs whose lyrics have been modified to be fitting with human research ethics.

“Overall, attendees found the conference highly invaluable as the programme offered a broad range of topics delivered by speakers from diverse backgrounds, opportunities to liaise and consult with affiliated partners and PRIM&R members, and most importantly, the chance to network and foster meaningful partnerships with other professionals who are also dedicated towards human research protection.”



Admin Roundtable at Khoo Teck Puat Hospital

Ng Hooi Ling
Executive
Clinical Research Unit
Alexandra Health

On 10 December 2010, the NHG Admin Roundtable was held at Khoo Teck Puat Hospital (KTPH). The event started with a guided tour around KTPH, the newest public hospital in Singapore. The hospital is set in a verdant landscape with flora and soothing water features; it is both “a hospital in a garden” and “a garden in a hospital”. The hospital also incorporates energy-efficiency in its design, it has solar panels to convert solar energy directly into electricity and a solar thermal system to produce hot water for the hospital’s needs. For the effort towards ensuring environmental sustainability, KTPH has been awarded the Building and Construction Authority (BCA) Green Mark Platinum Award. During the tour, participants were introduced to the new designs and amenities of KTPH such as the rooftop garden, clinics, subsidized wards, and not forgetting the Research Laboratory

After the tour, a presentation introducing the capabilities of KTPH’s Clinical Research Unit (CRU) was delivered by CRU’s Assistant Manager, Ms Joy Chan. Thereafter, the meeting ended with enjoyable fellowship accompanied by some light refreshments. KTPH CRU was set up to provide the infrastructure for the conduct of clinically relevant research with a comprehensive range of administrative, laboratory and clinical trial coordination capabilities. The research administration team facilitates and provides administrative support to both investigator-initiated and pharmaceutical-sponsored clinical trials. There is a team of research nurses comprising of registered

nurses with Good Clinical Practice (GCP) and Collaborative Institutional Training Initiative (CITI) certification working with multidisciplinary teams to provide nursing care in a research environment.

In addition to the core research facility, there is an Experimental Surgery Laboratory set up next to the mortuary to build up its research capability in developing new surgical skills and techniques. The laboratory offers facilities for cadaveric dissection in experimental procedures which makes it a suitable setting for holding courses and workshops on surgical procedures. This laboratory is equipped with freezers to store body parts, surgical equipment and energy sources.

“KTPH CRU also boasts the state-of-the-art Research Laboratory that provides centralized core-competent capability to the investigators given its long distance to other research institutions. Presently, the Research Laboratory has the following core capabilities: Molecular Genetics, Proteomics, Bio-banking, Cell Culture and Arterial Compliance. The following core capabilities will be added in the next few years: Immunohistochemistry, Bioinformatics and Medical Imaging (*Bio-imaging System*).”





Looking Back at Good Clinical Practice (GCP) Inspections in 2009-2010

Sumitra Sachidanandan

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

The Health Sciences Authority (HSA) launched the GCP Compliance Inspection Framework in Sep 2009. The objectives of GCP Inspections include safeguarding the rights, safety and well-being of subjects; verifying the quality and integrity of clinical trial data submitted to the Regulatory Authority; and assessing compliance to the protocol, Medicines (*Clinical Trials*) Regulations, Singapore Guidelines for Good Clinical Practice (SGGCP) and applicable standard operating procedures. GCP Inspections can either be routine, triggered or conducted in response to a pre-marketing approval application. The scope may involve trial sites, Phase I units, Sponsors including pharmaceutical companies and Contract Research Organizations (CROs).

The GCP Inspection process commences with a Notice of GCP Inspection being sent to the inspectee, including the principal investigator and sponsor, at least 30 working days in advance of the proposed date for GCP Inspection. The inspectee is then required to submit a GCP Inspection Dossier within 15 days. The GCP Inspection typically lasts about 2 days on site and comprises of an opening meeting, interviews with key study staff, facilities tour, document review and a closing meeting. GCP Inspection findings can be classified as critical, major, other or comments. A GCP Inspection Report is subsequently sent to the inspectee within 10 working days of the GCP Inspection. The inspectee is then required to submit a Corrective Action and Preventive Action (CAPA) Plan to HSA within 30 working days of receipt of the GCP Inspection Report. Once the CAPA is deemed to be adequate, the GCP Inspection is then considered closed.

HSA conducted a total of 13 GCP Inspections at trial sites between 2009 and 2010. This comprised of 12 routine and 1 triggered GCP Inspection. There was one 'critical' GCP Inspection Finding in the area of protocol compliance, 21 'major' GCP Inspection Findings and 73 'other' GCP Inspection Findings. Informed consent, Investigational Product and Study Staff accounted for the top three 'major' GCP Inspection Findings; whilst Investigational Products, Informed Consent and Case Review accounted for the top three 'other' GCP Inspection Findings.

For more information about the GCP Inspection Framework and HSA GCP Inspection Metrics for 2009-2010, please visit HSA's website ([Home > Health Product Regulations > Clinical Trials > Guidelines > Guideline on GCP Compliance Inspection Framework](#)).

“Another aspect of the GCP Inspection is also to educate study staff, Sponsors and CROs on clinical trials regulations and SGGCP through GCP Inspections. HSA has also embarked on preparing trial sites for GCP Inspections through SGGCP and NHG Training Courses (*such as Audits & Inspection Preparatory Workshop*), as well as sharing common GCP Inspection Findings through various conferences and forums.”





Institution Feature: National Healthcare Group Eye Institute (NHGEI)

The NHG Eye Institute (NHGEI) is established to oversee the provision of eye services throughout National Healthcare Group (NHG) and provide patients with greater convenience. To achieve this, all eye units and services of the cluster's hospitals are consolidated, together with the integration of primary and community units.

It provides services in 10 areas of specialisation:

- i. Cataract & Comprehensive Ophthalmology
- ii. Cornea
- iii. Glaucoma
- iv. Medical Retina
- v. Neuro-ophthalmology
- vi. Oculoplastics
- vii. Paediatric Ophthalmology & Adult Strabismus
- viii. Refractive Surgery
- ix. Surgical Retina
- x. Uveitis

NHGEI has also been actively developing collaborations with local and international research and academic institutions such as the Singapore Eye Research Institute (SERI) and Duke-NUS, as well as clinical research organisations to undertake significant clinical research of relevance to its patients.²

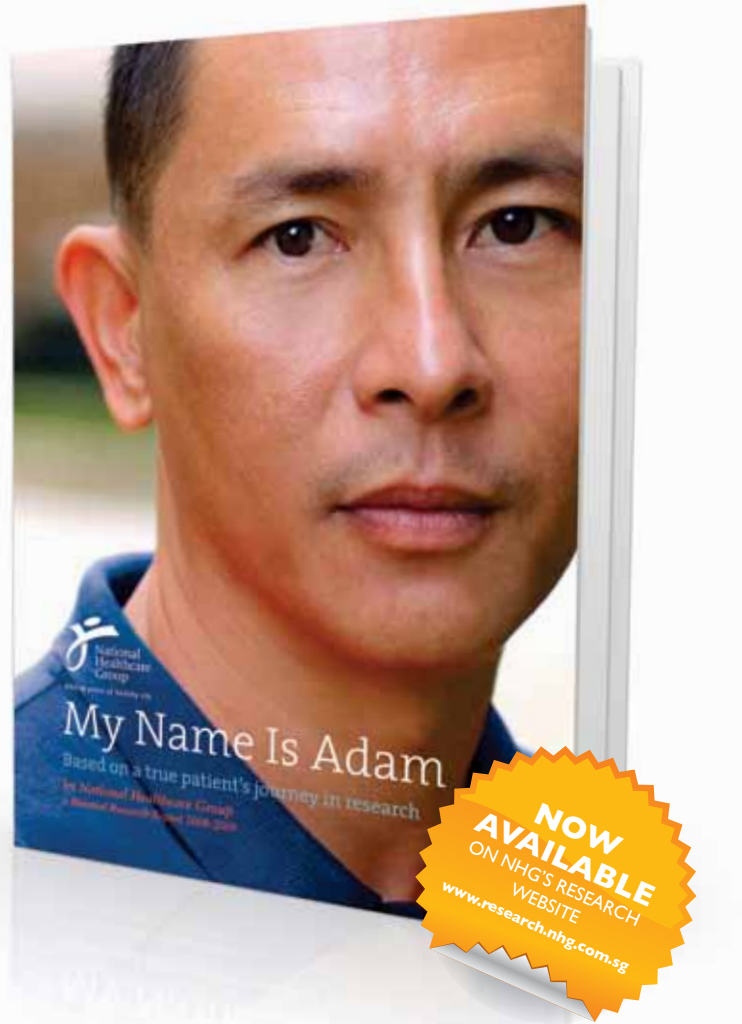
The NHGEI is located at Level 1 of Tan Tock Seng Hospital Medical Centre.

For more information on NHGEI, please visit their website at www.tei.com.sg.

Find out more about NHG Institutions and their research capabilities in our NHG Biennial Research Report 2008-2009

¹ National Healthcare Group Biennial Research Report 2008-2009. Chapter 2 – Understanding. Research Overview - NHG Eye Institute. Pg 50-35

² National Healthcare Group Eye Institute (NHGEI) website - www.tei.com.sg.

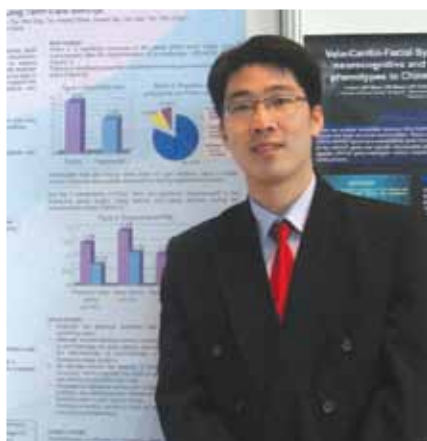


“A key capability of the NHGEI is Tele-Ophthalmology Service – a facility that allows patients to experience “live” video-consultation with a specialist at NHGEI from a remote location such as one of the NHG polyclinics. Launched in April 2009, this service aims to improve the accessibility of quality care and reduces the number of unnecessary patient referrals from polyclinics to specialist eye centres while maintaining a low rate of misdiagnosis.¹”



A Tribute to Allied Health Professionals

Email Interview with Mr. Zhou Zhenyu, APN Intern, Ward 33B, Institute of Mental Health (IMH) & Winner of the 1st Singapore Health and Biomedical Congress (SHBC) 2010 Scientific Competition Nursing Award (Poster ID: SG-NA-02)



Mr. Zhou Zhenyu is currently an Advanced Practice Nurse Intern (APN Intern) working in Institute of Mental Health (IMH) Singapore. He has been working in IMH for 8 years. He obtained his Master of Nursing (Mental Health) from National University of Singapore in June 2010.

As an APN Intern, Zhenyu is involved in clinical assessment and management of psychiatric patients, which includes mental state assessment, risk assessment, physical assessment, evaluation of the treatment modality and patient education. He is also actively involved in patient safety workgroups and various projects to promote safe clinical practice.

Zhenyu has great interest in research. He is a member of IMH Nursing Research Committee (NRC) and Evidenced Based Nursing (EBN) committee. He also heads the Nursing Journal Club of IMH to promote Evidenced Based Practice among nurses. Zhenyu has great interest in the sleep quality of psychiatric patients and has been leading a team in doing a study in this area.

What made you decide to be a nurse in this female dominated field?

I made my choice of becoming a mental health nurse when I came to Singapore. I believe mental health is an important part in everyone's life and mental health nursing is the profession which touches the souls of human beings.

How do you feel about winning the Gold Award in the SHBC 2010 Scientific Competition last year? Can you share briefly on the research you have conducted?

In my opinion, the win was not mine but of the whole research team. Without their hard work of our team members, and support from Dept of Nursing IMH, the award winning could not be possible. This award is also a recognition for the work done by the research and nursing teams involved in the study.

We initially planned this research project as we observed that many of our patients in long stay psychiatric ward had sleeping difficulties, Therefore we wanted to look for some possible alternatives. This study suggests that 2 drops of lavender oil can help patients with schizophrenia to sleep better, and cut down their consumption of sleeping pills.

Given the high demands of the job, what motivates you to do research?

- Research is something that we can do to move our profession forward. With the development of new knowledge by research, it builds up the scientific base of our specialty, which will improve our healthcare outcome eventually.
- The guidance from supervisors and support from team members are also crucial motivating factors.
- Participants' positive feedback and clinical outcomes never fail to give me a sense of satisfaction.

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

Finding time to do research is probably the most challenging part. This is a problem not only faced by me, but also by my team members. It was very hard to find time to meet up, as we had our own clinical work to do, and most of us doing shift work. We had to arrange meetings way in advance, so that we can plan our schedule. If we really cannot meet up with all members present, then we will communicate through email and telephone. To get the work done, we always need to work during our off days or even during leave period.

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

We are very glad that our participants showed good response and benefited from the research study. Some of the participants requested to continue using aromatherapy after our study ended, which gave us the greatest satisfaction. We hope that more studies can be done in this specific area and aromatherapy could be adopted into clinical practice in future.

How do you handle the tight demands of your schedule?

Prioritize and prioritize. Squeeze time and squeeze more time.

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

Of course, the most memorable would be winning the award. Some others include seeing our posters being presented at prestigious conferences.



Small Innovative Grant I (SIG I) Awardee – A Chance Beginning



Dr Lim Choon Guan
*Department of Child & Adolescent Psychiatry
Institute of Mental Health*

It was my supervisor who encouraged me to sign up for the inaugural NHG-NUS Clinician Leadership in Research Programme in 2007. He connected with the dean of Duke-NUS GMS, who was keen to test an ‘attention training device’ which involved the use of a brain-computer interface, developed jointly with a group of brilliant engineers from A*STAR. I was immediately interested: can this help children with attention deficit hyperactivity disorder (ADHD)? We designed a pilot trial to test out its efficacy.

The Small Innovative Grant (SIG) seemed perfect for this project. I needed a therapist to administer the intensive training programme (20 sessions over 10 weeks). Hiring a research associate was the next challenge. A competent therapist was necessary, and he or she could make

or break the project. We foresee having to keep our hyperactive participants engaged, persuading parents to keep to the intensive intervention schedule and having to constantly bug irate teachers to complete and return questionnaires. That was how Stephanie, my research associate and therapist, joined me on the project, and the rest was history.

Fast forward 4 years now, we have successfully presented our findings at the exclusive 48th American College of Neuropsychopharmacology meeting, published our findings and even obtained a joint patent with Duke-NUS and A*STAR for our training device. We have further improved our device with ‘dry sensors’ and bluetooth technology to replace the cumbersome electroencephalogram (EEG) cap and messy wires. We have also improved the ‘fun’ factor of our training programme and will be embarking on a larger-scale randomized controlled trial (RCT) soon.

“Looking back, all these would not have been possible if not for the SIG. We have since ‘expanded’ to a team with two other research associates, and are hopeful that we will one day develop an effective yet fun treatment for ADHD, for administration in the comfort of the child’s home.”



Isolation and Characterisation of a Novel Stem Cell Population from Human Umbilical Cord

Dr Leonard Ang Pek-Kiang
Medical Director and Senior Consultant
Ophthalmologist
The Eye & Cornea Transplant Centre

Stem cells have tremendous regenerative ability and have the potential to treat an enormous range of diseases. Most of the clinical applications of stem cells have been using adult stem cells. However, there are limitations with its use because of its limited proliferative ability and the difficulty culturing these cells outside the body. Embryonic stem cells (ESC) and Induced pluripotent stem cells (iPSC) are also potential stem cell sources but there are major issues relating to their use, such as the ethical concerns of ESC and the tendency to form tumours in ESC and iPSC.

Umbilical cord tissue and cord blood are promising alternative stem cells sources. Cord blood stem cells are rich in haematopoietic (*blood*) cells, but lack sufficient mesenchymal and epithelial stem cells for regenerating solid organs in the body.

We hypothesized that human umbilical cord harbors many cell types, which could be effectively isolated for treating various diseases. These may overcome the limitations associated with the use of adult stem cells, ESC and iPSC. The aims of our study are to isolate a novel stem cell population from umbilical cord and to be able to inducing these cells to differentiate into an epithelial cell type that could be used for tissue regeneration.

We surgically dissected the umbilical cord lining membrane from the Wharton's jelly and other internal structures. The cord lining cells were cultured in a specialized PTE-1 culture medium. We successfully isolated and characterized a novel cell type expressing MUCIN1 (CD227) (Fig. 1) from human umbilical cord lining which we termed MUCIN-expressing Cord Lining Epithelial Cell (CLEC-muc).

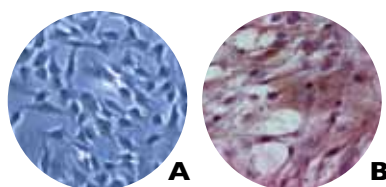


Fig 1. Features of CLEC-muc

A. Appearance of CLEC-muc
B. DAB staining showing abundant expression of Mucin1 (CD227).

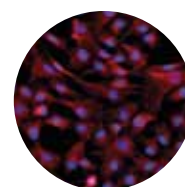


Fig 2. CLEC-muc were induced to form a cornea-like epithelial sheet expressing CK3/CK12 (red staining)

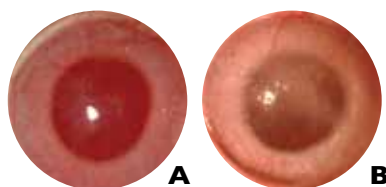


Fig 3. Transplantation of cultured CLEC-muc onto damaged rabbit eyes

A. CLEC-muc transplanted eye showing a clear and smooth cornea surface
B. No CLEC-muc

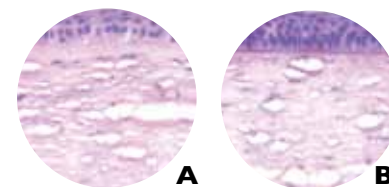


Fig 4. Histological appearance of transplanted cultured CLEC-muc was similar to normal in vivo cornea epithelium

A. Transplanted CLEC-muc sheet
B. Normal cornea

CLECs-muc differed from other known stem cells in terms of their appearance and cellular characteristics. These cells were highly proliferative and possessed both epithelial and mesenchymal stem cell characteristics. The cells exhibited both embryonic and adult stem cell properties with expression of embryonic (*Oct-4, Nanog, Sox2, Rex1, SSEA-4*) and adult (*p63, ABCG2*) stem cell markers. The cells were found to be less immunogenic, meaning that the risk of graft rejection was lower.

We subsequently induced these cells to differentiate into a highly specialised cornea-like epithelium which expressed cornea-specific cytokeratins CK3/CK12 (Fig. 2). To evaluate the in vivo regenerative ability of these cells, we transplanted cultured CLEC-muc sheets onto rabbit eyes that were devoid of cornea epithelium and cornea stem cells. We found that the transplanted cells

were able to successfully regenerate a smooth and clear corneal surface (Figs. 3 and 4). CLECs-muc were found to be non-tumorigenic.

In summary, we successfully isolated a novel stem cell population, CLEC-muc, that exhibited mesenchymal and epithelial stem cell characteristics. CLEC-muc has advantages over other stem cell sources (such as adult stem cells, ESC and iPSC), because it is easily obtainable, has no ethical issues related to its use, is highly proliferative, and does not form tumours.

CLEC-muc may serve as a readily available source of stem cells that may prove to be a better and safer stem cell source. These novel stem cells have potentially important clinical applications for use in regenerative medicine and tissue replacement for treating various diseases.

A Clinical Trials Manual from the Duke Clinical Research Institute

Lessons from a Horse Named Jim, 2nd Edition, by **Margaret Liu and Kate Davis**

Authored by both Margaret Liu (a clinical trials consultant based in Singapore and former manager of the Monitoring Group at the Duke Clinical Research Institute (DCRI)) and Kate Davis (a Business Development Specialist for DCRI Communications Group, Durham, NC, US), the manual is indeed a truly comprehensive reference guide and manual for anyone conducting or involved in the process of coordinating, managing and overseeing clinical trial regardless of the role one plays (Investigator, CRC, Monitor or a CRO).

This manual begins with an overview of the historical framework of the clinical

research, rules and regulations that govern clinical trials, the process of development for drugs, biologics and devices. It also provides very useful information, comprehensive and practical tips for the conduct of clinical trial at investigative sites. The manual also provides guidance on how trials are to be conducted at the investigative sites.

The topics covered are very wide – these include Good Clinical Practice, informed consent and the regulations, Institutional Review Boards, reporting of adverse events and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSTO), monitoring, audits, and inspections, responsibilities of the Principal



Investigator and study site staff, study protocol and so forth.

It is indeed a very readable and comprehensive manual one can rely on to provide basic and in-depth information about each segment of a clinical trial. Sample forms, logs and worksheets are also provided as reference. “A Clinical Trials Manual” is available for purchase at Amazon.com or through Wiley Asia’s sales representative.

PCR Teasers

NHG’s Proper Conduct of Research (PCR) courses are designed to provide Investigators and Clinical Research Coordinators with foundational knowledge of good research practices and to familiarize them with the regulatory requirements and good clinical practice guidelines. There are 3 levels to the PCR courses - Basic, Intermediate and Advanced. **Below are a few questions taken from the PCR Basic Courses. Try them!**

Question 1: In June 1964, the 18th World Medical Association General Assembly, developed a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. What is this statement called?

- (a) The Nuremberg Code
- (b) Declaration of Helsinki
- (c) The Belmont Report
- (d) All the above

Question 2: Dr Brain thought that Mr Kun Fu Shun was eligible for participation in a research study for Parkinson’s Disease. Dr Brain was doubtful whether Mr Kun was capable of giving informed consent. Which one of the following is least accurate?

- (a) Dr Brain should obtain for an independent doctor’s written certification that that subject was not capable of giving consent.
- (b) Dr Brain should conduct a complete informed consent discussion with the subject’s wife, Madam Kun Fu Shun.
- (c) Dr Brain should try to explain the study in very simple words to Mr Kun.
- (d) Dr Brain should obtain written certification from the sub-investigators that the subject would benefit from participation in the study.

Question 3: Which situation is most likely to qualify for waiver of documentation of informed consent because documentation places the subject at risk of harm?

- (a) A face to face interview with drug abusers.
- (b) A focus group with patients who survived cancer.
- (c) A clinical trial testing efficacy of two over the counter medicine
- (d) A study that involves use of left over tissue.

Did you get them right?

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



NHG Office of Human Research Protection Programme (OHRPP)

The NHG Research & Development Office (RDO) is proud to announce the formation of the Office of Human Research Protection Programme (OHRPP). Echoing RDO's mission of "translating research into highest quality patient care", the OHRPP strives to promote and facilitate the ethical conduct of human subject research in NHG and partner institutions.

The OHRPP's goals are to ensure the safety and well-being of human research participants, and to advocate their rights through (a) efficient and high quality ethics review (b) education on human research protection (c) quality assurance and continuous improvement (d) engagement of public and research partners.

Under the OHRPP, existing divisions which oversee the conduct of human research are regrouped, and new divisions are added to provide better support and completeness to the programme.

DSRB Operations & Management

Formed in 2004, the DSRB has been providing ethics review of research protocols in NHG and partner institutions to ensure that the rights, safety and welfare of patients and participants are well protected. The DSRB is also the first public healthcare ethics review board outside North America to be accredited by the Association for Accreditation of Human Research Protection Program Inc. (AHRPP) in March 2007.

As a commitment to ensuring that our members and staff have the professional relevance and knowledge in performing ethics review, the DSRB has in place continuing education initiatives, notably the Certified IRB Professional (CIP®) certification, as well as the AAHRPP and Public Responsibility in Medicine & Research (PRIM&R) conferences.

On top of the current 5 biomedical boards, a new board is being established to review population and community health research.

Research Quality Management

The Research Quality Management (RQM) is the next division under the OHRPP. RQM formally started as a division providing quality assurance activities to ensure that research protocols are carried out ethically and in accordance with the Singapore Guidelines for Good Clinical Practice (SGGCP), Proper Conduct of Research (PCR) SOPs, DSRB SOPs and other applicable regulations. In addition, RQM extended monitoring for selected Investigator-initiated Studies (IIS) to support investigators

in ensuring data quality and compliance. In August 2009, RQM introduced and implemented the investigator self-assessment checklist as a tool to reach out to the research community at large. Under OHRPP, the RQM division will undertake to review quality in different stages of the research process and to develop quality improvement initiatives. Two such areas are in optimising the DSRB's operational efficiency, and in creating tools and training to support investigators conducting IIS.

Researcher Training & Support

The Researcher Training & Support (RTS) is responsible for content management of training programmes and for implementing support initiatives for researchers and research support staff. The better known training programme under the RTS are the Proper Conduct of Research (PCR) courses, which comprise 3 foundational modules (PC101-103), 1 intermediate module (PC201) and 2 advanced modules (PC301-302). In September 2010, the PC101-103 modules were introduced online and made accessible to a larger group of participants within and outside NHG.

The RTS division also oversees the publication of the *Qualité Newsletter* and *Chicken Soup for the Busy Coordinator*, both of which offer information on research best practices and provide explanations on critical issues surrounding research. In addition, the RTS division collaborates closely with institutions and industry partners to organise training forums, namely the Clinical Research Coordinators Society (CRCS) Forums and the Clinical Research Professionals (CRP) Forum.

In view of the expanding training needs of researchers and research support staff, the RTS will be introducing a series of departmental seminars or lunch-time talks. One such talk will be on the DSRB Application and Submission, which is intended to familiarise researchers with questions on the application form and techniques to answer and complete the form.

Responsible Conduct of Research

The Responsible Conduct of Research (RCR) division will oversee the propagation of RCR culture and education within the research community. While Proper Conduct of Research shares knowledge on doing things right, RCR looks at doing the right things. Although research regulations and guidelines abound, there still exists instances where there are no clear-cut answers. At times like these, individual values and integrity may be challenged, and the onus falls upon the researcher to

determine what is right. The RCR division intends to develop a set of research best practices to address tricky issues, such as in areas of Research Misconduct, Protection of Human Subjects, Conflicts of Interest, Data Management Practices, Mentor and Trainee Responsibilities, Collaborative Research, Authorship and Publication, and Peer Review.

Collaboration & Partnership

The Collaboration & Partnership (C&P) division oversees the extension of ethics review services and oversight to external healthcare set-ups and agencies. In 2010, NHG DSRB embarked on providing ethical oversight to St Luke's Hospital, Dover Park Hospice, Health Sciences Authority, Jurong Health Services, and the Agency for Integrated Care. Such research partnerships between healthcare institutions provides a common platform of ethics review and establishes common standards of research conduct in the different institutions. Through the C&P, the OHRPP will expand its pilot projects of general public forums and participant brochures to targeted sectors of the populations (e.g. schools or health care providers in the community). It is also recognised that as NHG embarks on population health management, greater interaction with the general public is expected, and hence the importance of community outreach as well. An enhanced public outreach programme supports this initiative.

The formation of the OHRPP signifies NHG's commitment to protecting research participants through a comprehensive setup of programmes, framework and functions. With greater autonomy, the OHRPP is better able to drive improvement and innovation that can directly benefit the research community. The OHRPP will continue to forge close partnerships with institutions and agencies within and outside NHG, while promoting community outreach and education for the public. The OHRPP will also take the lead in advocating best practices in human research protection through merging knowledge and experience learnt from our counterparts in the West and implementing them in Asia's context.

For enquiries, please contact:

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Knowing Our Healthcare Leaders



Professor Martyn R Partridge

Martyn Partridge is Senior Vice Dean, The Lee Kong Chian School of Medicine, a joint Medical School by Imperial College London and Nanyang Technological University Singapore. He is also Professor of Respiratory Medicine at Imperial College London. After early work on chemotherapy for lung cancer and study of the site of airflow limitation in asthma, his more recent research has concentrated upon evaluating the delivery of healthcare to those with respiratory illnesses. This includes evaluation of service enhancements such as telephone consultations, use of lay educators, Electronic asthma and COPD action plans, and methods of enhancing communication between both patients and doctors, and specialists and GPs. He has a particular interest in the subject of health literacy and in simplifying information materials and questionnaires (such as the Epworth score) to enhance widespread comprehension.

An essential part of good healthcare is a well trained workforce and Professor Partridge chairs the clinical years sub-committee of the Undergraduate Education Committee at Imperial College where he is also Deputy Director of Education.

Professor Partridge is past President of the British Thoracic Society (BTS), previous Chief Medical Adviser to Asthma UK and he currently chairs the UK Department of Health Asthma Steering Group and is on the DH Respiratory Programme board.

He moved to his current position in October 2010 and now spends most of his time in Singapore.

www.imperial.ac.uk/medicine/people/m.partridge

Interview

Martyn R Partridge
Senior Vice Dean
Lee Kong Chian School of Medicine

A joint medical school by Imperial College London and Nanyang Technological University, Singapore & Professor of Respiratory Medicine and Deputy Director of Education (Medicine) Imperial College London

MEDICAL EDUCATION

What do you believe to be the ideal type of education for a medical doctor?

The medical graduates of most medical schools become general practitioners, family physicians, hospital specialists, clinical scientists, medical teachers and medical administrators. We therefore have to design a medical course that covers such pluripotentiality.

This involves a strong emphasis on the scientific basis of medicine coupled with an understanding of the clinical relevance of that science and all moulded into an approach which is patient-centred and cognisant of the importance of shared decision-making. To deliver such an education involves the highest quality of teachers practising within a university and

healthcare system which understands and values the importance of teaching, and which uses all modern learning methodologies, whether e-learning, small group interactive seminars, team-based learning, problem-based learning or apprenticeship.

How will this third medical school in Singapore develop medical doctors who can be proficient in both scientific research and medicine?

Understanding the scientific basis of medicine is a basic pre-requisite for lifelong learning and our students have to understand that during the course of their professional life, they will be faced with new diseases and new treatments. We hope that they themselves will be involved in some of those developments and to enhance

clinical science, we need appropriate role models and the students need to be enthused with the excitement of science and discovery.

Critical appraisal skills will play a prominent role within the course and in their 3rd and 4th years, time is set aside over a two-year period for the students to undertake some research so that they may explore areas of scientific interest in greater depth.

In particular how do you aim to 'inculcate our graduates with a resolve to always provide a service to their patients which is, at a minimum, equivalent to that which one would receive from a top restaurant or hotel'? What would be the key approaches and strategies?



Interview

Our aim is to produce graduates who would provide care of the standard that we would wish for if we were ourselves the patients. In part, this involves careful selection of those with the appropriate characteristics for entry into the medical school and considerable thought has already gone into our selection process which will utilise multiple mini interviews to enable us to test applicants' sense of duty, service, empathy and communication skills. This will be coupled with formal assessment of scientific aptitude by use of the Bio-Medical Admissions Test (BMAT) which will be taken by all applicants to the new medical school.

How would you measure success of the third medical school?

Like all academic institutions, the medical school will be assessed on the basis of the quality of both its teaching and its research. To provide and nurture the right scientific environment of the medical school will involve employment of high quality academics who will maintain a high quality research program attracting significant research monies and with outputs of publications in top cited journals. Teaching standards will be carefully monitored and regular quality assessment undertaken in line with the processes in use at Imperial College London but the best outcome will be for our graduates to be ambassadors for the new school, for them to be keenly sought by healthcare organisations and to be acknowledged by patients for their kindness, care, skill and professionalism.

Is there an ideal student profile/special quality in students that you foresee at the third medical school?

Medicine is a popular career aspiration amongst the young in Singapore and sadly the current shortage of medical school places means that many fine candidates are not able to achieve their ambition. We are thus likely to be blessed with academically able students but in addition we wish to admit those with positive attributes in terms of professionalism, duty and empathy.

Are there any new initiatives in imparting knowledge or research that you would like to see implemented at this third medical school?

In terms of curriculum development and delivery, we will be bringing the best parts of the Imperial College London course to Singapore but have started with a fresh sheet of paper which gives us an opportunity to be innovative. The Lee Kong Chian School of Medicine course will involve early patient contact with the science being distributed throughout the five-year course. Current medical education is often too hospital-centric and learning opportunities are often under-used in polyclinics, primary care, rehabilitation centres and step-down hospitals.

Within these environments, students can equally attain good clinical skills and practise with optimal communication and we will make every effort to avoid our students acquiring a short-term approach to illness which is often the misconception achieved if training is only undertaken in acute hospitals. Much of medical care today involves people who are often elderly living with long-term medical conditions and students need to acquire the appropriate skills to support patients as they themselves manage their own conditions.

However, this needs to be balanced by a realisation that technology has much to offer the modern physician whether by application of bioengineering and materials technology or by use of computers for bioinformatics or for decision support making. Lee Kong Chian School of Medicine has an almost unique opportunity to capitalise on the strengths in these fields which exist at Nanyang Technological University.

Teachers from the College of Engineering and Business School are already involved in helping us formulate our curriculum. Imperial College London has immense experience in the use and evaluation of e-learning and these techniques will be embedded within the Lee Kong Chian School of Medicine course.

TRANSLATIONAL MEDICINE

Translational medicine is increasingly recognised as being of paramount importance and our students' exposure to the values of biotechnology and business school methodologies will equip them well to cope with the new way in which healthcare is being delivered.

There is increasing evidence that within the Singapore healthcare system, process mapping, systems change and use of technology is altering the whole way in which healthcare is being delivered and whilst this is most apparent in hospitals at the present time the whole area of telehealth and telemonitoring is going to be increasingly important as integrated care gains in prominence. Care of the right sort delivered at the right time where the patient needs it is the way forward, and our understanding of the importance of integrated care and better care in the community is demonstrated by one of our first faculty appointments being in this field.

ON A LIGHTER NOTE

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

Like many of my generation, I am sure that I have failed to get the work-life balance optimally arranged! Married to a doctor and with 3 children who are doctors even the dinner table topics can reinforce the wrong balance! But the privilege of travel and the privilege of working with medical colleagues over many years on many continents and now especially in Singapore has brought with it a whole range of activities which whilst based upon work, are nevertheless nothing other than relaxing and exciting. In the 9 months or so since I have been coming to Singapore, I have also visited Hong Kong, Malaysia, India (twice), Indonesia and Vietnam. In the past my children were brought up in a house that was always full of visitors from overseas whether from Pakistan, the Caribbean, Albania or South America – it was a great way of getting them to learn their Geography!

NHG Research Online Administration & Management (ROAM)

NHG will be upgrading its online ethics platform to a new platform called NHG ROAM (Research Online Administration & Management) in Q2, 2011.

Yeo Kian Wah, CIP
IT Administrator
Research & Development Office
National Healthcare Group

NHG ROAM is intended to expand the current system's capabilities in several aspects by improving the current online DSRB application process as well as adding innovative solutions via 3 main user friendly modules:

- Ethics Application, Review & Approval Module
- Research Quality Assurance (RQA) Module
- Events Listing & Registration Module

The change-over to NHG-ROAM will directly affect you as a user of the NHG Research portal. There are three main critical areas which you must be aware of:

Verification of existing NHG Research Accounts

We will need ALL USERS to update their online accounts with a valid NRIC/FIN number. This information is crucial for the successful migration of studies and is the only form of identification recognized by the NHG ROAM system. In addition, users must also verify that all other account details (*e.g. Department, Institution*) are current and correct.

NHG ROAM Information Sessions and Hands-On sessions

There will be information sessions as well as Hands-On Sessions organized for the research community to familiarize you with the ROAM system. Visit our website (www.research.nhg.com.sg) for the latest schedule.

Migration of Paper-based DSRB Submissions

As part of the upgrading, all paper-based DSRB submissions (*current ongoing studies which were first submitted between 2004 and 2008*) will be migrated to the new NHG ROAM system. We will be contacting the Principal Investigators of these studies for validation of study information. Visit our website for more information. We will be releasing more information about the launch soon. So check www.research.nhg.com.sg regularly for the latest updates! For any queries, do drop us a line at researchonline@nhg.com.sg.

We thank you for your cooperation in our collective effort to promote high quality and ethical research in NHG and our partner institutions.



Fraud and Data Falsification Left UK Close to Endemic Measles

In 1998, a researcher in a study allegedly falsified study data in order to draw an intended link between a triple vaccine and autism to satisfy a group's biased self-belief. This irresponsible and deliberate malice led to severe consequences which included the exposure of hundreds of thousands of children in Britain to Measles, Mumps and Rubella (MMR).

Find out more about this infamous alleged study of fraud and data falsification here:
www.channelnewsasia.com/stories/health/view/1103018/1/.html

Contributed by the Responsible Conduct of Research (RCR) team at NHG Research & Development Office (RDO)



Reference Management for the Busy Researcher



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Chong Xiao Yun & Jolene Poon
WizFolio

Accelerate your research process with WizFolio

One annoyance that researchers have when doing research and Continuing Medical Education (CME) is navigating the many pages of the Publisher's website to get to the PDF article they are interested in.

To get to the elusive article, they would most probably have to do this through a library subscription, which means logging into the library -more navigation! In this information age, spending so much time on such menial tasks should be a thing of a past. Introducing the WizFolio's "Locate PDF feature – a faster way achieving what used to consume hours with just a click! This software works in the background to navigating the pages for you, leaving only your PDFs at your fingertips. Traditional reference management software helps you organize your references very well. However, they fall short when it comes to collaborative work. Bringing minds with different expertise together is an extremely good idea but it comes with much hassle. Manually sharing lists of references meant that your colleague had to go through those references and organise them himself. WizFolio addresses this issue by providing

you with several options. There are a couple of ways to share references. One useful way is to invite your collaborators as colleagues. You can grant colleagues access to your file with its organisational structure intact. If you find adding colleagues inconvenient, you can Tweet, Facebook, email references lists, or set up a webpage quickly.

Previously, if you need to do collaborative citing, you would hesitate to modify the citations of a colleague's document, especially if different operating systems or w/p are involved. WizFolio users will not face such complications as it works on Mac, Windows and Linux, and on word processors such as Microsoft Word and Open Office. Dr Casey Chan (Chief Architect of WizFolio) describes WizFolio as "cross platform and word processor agnostic".

Bring it further with the iPad

Furthermore, due to heavy workloads and the need to keep up with new medical information, many clinicians and researchers are finding the iPad a convenient device to access information on the go. The iPad is highly optimised for viewing PDFs; clinicians can work comfortably, zooming and scrolling PDF documents. With the slimmer and faster iPad 2, clinicians and researchers will find this even more compelling.

WizFolio enables the handling of quick note taking and viewing of references. Its greatest value is its hybrid compatibility with multiple devices, especially the iPad.

The convenience that WizFolio brings stems from the fact that it is a web-based application. This means that you need only work on one set of information regardless of which device you access WizFolio. This removes the need for preloading, organising, and consolidating research information for each device. You would never have to worry about server crashes or information loss as the data on the server is backed up.

The benefits of quick access to your information does not stop here. One can expect many situations where this will come in handy. One can already imagine clinicians making quick references to data on WizFolio while seeing patients or keeping up with CME during breaks. If you have not decided, now is the time to take the plunge!

WizFolio is an online research collaboration tool for knowledge discovery. With WizFolio you can easily manage and share all types of information in a citation ready format including research papers, patents, documents, books, YouTube videos, web snippets and a lot more. Visit WizFolio at www.wizfolio.com.

Watch the **WizFolio iPad demo on YouTube** at <http://goo.gl/VZyf4>

Results of NHG FY2011

Small Innovative Grant (SIG I) Grant Calls

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 November 2010 last year, the Small Innovative Grant (SIG) and the was launched. Below are the results from the grant call:

Small Innovative Grant (SIG I) Awardees

S/N	Project Title	Principal Investigators	Institution	Department
1	An evaluation of Medisave Liberalisation for Diabetic patients in the National Healthcare Group	Ms Tan Woan Shin	HQ	Health Services & Outcomes Research
2	The frequency of anti-NMDA receptor and anti-VGKC encephalitides in patients presenting with acute psychosis	A/Prof Swapna Verma	IMH	Department of Early Psychosis Intervention
3	Progressive brain abnormalities and their relationship to outcome in schizophrenia: a longitudinal structural magnetic resonance and diffusion tensor imaging study	Dr Sim Kang	IMH	Department of General Psychiatry
4	Pilot study of comparative analysis of the tear protein profile in Pseudomonas Aeruginosa Keratitis patients	Dr Don Pek Chern Kuok	TTSH	Ophthalmology
5	Optimising hormonal therapy in hormone responsive breast cancer	Dr Tan Ern Yu	TTSH	General Surgery
6	Quality of life and resource utilisation in mild-moderate dementia patients - An Asian perspective	Dr Chong Mei Sian	TTSH	Department of Geriatric Medicine
7	Prospective Evaluation of Retinal Vascular Parametric Changes in Patients with HIV	Dr Stephen Teoh Charn Beng	TTSH	Ophthalmology
8	A pilot randomised control study to assess the efficacy and safety of oral valganciclovir as an adjunctive versus steroids monotherapy for CMV-associated immune recovery uveitis in immunocompromised patients	Dr Stephen Teoh Charn Beng	TTSH	Ophthalmology



Clinical Leadership in Research (CLR) Grant Calls

The Clinician Leadership in Research (CLR) is a 2 year program that consists of 3 components: Mentorship, Training and Assessment. Successful applicants explore collaborative opportunities with their nominated mentors and receive seed funding and academic allowances to support these research projects.

In November 2010 last year, the Clinician Leadership in Research (CLR) was launched. Below are the results from the grant call:

Clinician Leadership in Research (CLR) Awardees

S/N	Project Title	Principal Investigator	Institution	Department
1	The Prevalence Of Microalbuminuria And Macroalbuminuria In Type 2 Diabetic Patients In The Primary Care Setting Of A Public Institution In Singapore	Dr Lee Eng Sing	NHGP	Clementi Polyclinic
2	A study of the impact of photograph-assisted dietary review amongst type 2 diabetics in a Primary Care Setting	Dr Darren Seah Ee-Jin	NHGP	Toa Payoh Polyclinic
3	A Pilot Study of the Long Term Psychiatric, Neurobehavioral and Psychosocial Outcomes after Traumatic Brain Injury	Dr Chan Lai Gwen	TTSH	Psychological Medicine
4	Accuracy of Emergency Physician-Performed Ultrasonography in detecting Deep Vein Thrombosis	Dr Teo Ying Xin	TTSH	Emergency Department
5	Refinement of a triage electrocardiogram protocol at the Emergency Department	Dr See Keng Kew Terence	TTSH	Emergency Department
6	Comparison of arterial & venous blood gas values in patients with respiratory and metabolic emergencies	Dr Saclolo Rafael Pulido	TTSH	Emergency Department

Upcoming Grant Calls in Singapore

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

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

Eligibility

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

Funding

The maximum funded amount for each project is S\$300,000 for a maximum period of 3 years.

The grant call will be open twice a year in January and July. More information can be found on NKF's website at www.nkfs.org.

2. BMRC-SERC Diagnostics Grant Call

The Nutrition and Food Science Grant Call is funded by A*STAR and jointly managed by the Science and Engineering Research (SERC) and Biomedical Research Council (BMRC). This call aims to boost Singapore's strategic intent to develop its food and nutrition industry.

Eligibility

The Principal Investigator for the proposal must be primarily employed in the public sector and fulfill the following conditions:

- Possess a minimum academic qualification of a Bachelors degree; and
- Reside in Singapore for at least 9 months in a year

Funding

A total of \$8 million has been allocated for this grant call. Successful applications will receive up to \$1 million funding for 2 to 3 years.

The grant call will be open on 15 July 2011 for a month. More information can be found on A*STAR's website at www.a-star.edu.sg

NHG Research Training Calendar

for June - September 2011

Date	Time	Course Title	Course Category	Course Module	Venue	Seats
Ongoing	00:00-23:59	Proper Conduct of Research Online – Basic I-III	Proper Conduct of Research	PC101-103	www.elearning.nhg.edu.sg	120
27 June	13:30 -17:40	Research Governance, Informed Consent and Institutional Review Board (IRB) Workshop	Research Ethics	RE101C	National University Hospital, Kent Ridge Wing Level 2, ASTC, STLab	30
8 July	13:30 – 17:45	Documentation and Audits Workshop	Research Ethics	RE104C	Civil Service College, Training Room 4.3 (Level 4), 31 North Buona Vista Road	30
18-19 July	08:30 – 18:00	Basic Biostatistics and Research Design Workshop	Research Methodology	RM101C	PSB Academy, Blk A, Level 2, A-204 & Blk E, Level 2, E-206	30
20 July	09:00 – 17:30	Intermediate Biostatistics Workshop	Research Methodology	RM102C	PSB Academy Blk E, Level 2, E-206	30
4 Aug	14:30 -17:30	Combined CRP-CRCS Forum	–	–	Civil Service College, Auditorium, 31 North Buona Vista Road	300
26 Aug	TBC	Abstract and Manuscript Writing	Research Methodology	RM103E	TBC	30
8-9 Sept	09:00 – 18:00	Singapore Guidelines to Good Clinical Practice	–	–	National University Hospital, Kent Ridge Wing Level 2, ASTC, Seminar Hall	60
30 Sept	TBC	Grant Preparatory & Poster Presentation Seminar	Research Methodology	RM105E	TBC	30

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

NHG Institutions Training Calendar

for July - September 2011

Date	Time	Training Programme	Course	Venue
1 July	8.30am - 5.30pm	Finance Course for Clinicians & Managers	Medical	NHG College, Jackson Square
16 July	8.30am - 5.30pm	MRCP PACES Practice Exam	Medical	Day Surgery Ward, NUH
21 July	9.00am - 12.30pm	Mastering Your Risk	Medical	NHG College, Jackson Square
21 July	1.30pm - 4.30pm	Mastering Adverse Outcomes	Medical	NHG College, Jackson Square
22 July	9.00am - 12.30pm	Mastering Your Risk	Medical	NHG College, Jackson Square
22 July	1.30pm - 4.30pm	Mastering Difficult Patient Interactions	Medical	NHG College, Jackson Square
30 July	8.30am - 12.30pm	The Sedation Course for Non-Anaesthetists	Medical	NHG College, Jackson Square
4 & 5 July	8.30am - 5.00pm	Risk Management & Patient Safety Course for ANs/ SANs	Nursing	NHG College, Jackson Square
6 July	8.30am - 5.00pm	Patient Teaching Course for ANs	Nursing	NHG College, Jackson Square
27 & 28 July	8.30am - 5.00pm	Risk Management & Patient Safety Course for RNs	Nursing	NHG College, Jackson Square
29 July	8.30am - 5.00pm	Coaching Skills Course for SANs	Nursing	NHG College, Jackson Square
11 July - 5 Aug	8.30am - 5.00pm	Clinical Instructors' Course	Nursing	NHG College, Jackson Square

For registration and full details, please visit www.nhg.com.sg/College/.

QUALITÉ

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

ISSUE 2011/06

+ PARTICIPANT INFORMATION SHEET READABILITY

Developing a Readable Participant Information Sheet. Find out how you can make the Participant Information Sheet simpler and what is the appropriate literacy level for Singapore.

+ THE PRINCIPAL INVESTIGATOR'S ROLES & RESPONSIBILITIES (Part 3/5 series)

No.5: Communicate with regulatory agencies and obtain approval to conduct study

No.6: Assure protocol compliance throughout study

PARTICIPANT

INFORMATION SHEET READABILITY

The Participant Information Sheet serves as a guide when describing to subjects all the necessary information they need in order to make an informed decision about participating in the study. Being medically-trained by profession, most investigators tend to use technical and scientific terms when constructing the participant information sheet. A Participant Information Sheet containing technical and scientific jargons can hinder the subject's understanding and comprehension of what the research study actually entails. Subjects may not fully grasp the risks and benefits associated with the trial or research.



The Participant Information Sheet serves as a guide when describing to subjects all the necessary information they need in order to make an informed decision about participating in the study. Being medically-trained by profession, most investigators tend to use technical and scientific terms when constructing the participant information sheet. A Participant Information Sheet containing technical and scientific jargons can hinder the subject’s understanding and comprehension of what the research study actually entails. Subjects may not fully grasp the risks and benefits associated with the trial or research.

The Singapore Guideline for Good Clinical Practice (SGGCP) provides guidance on how the Participant Information Sheet should be constructed. SGGCP 4.8.6 says that, “The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject’s legally acceptable representative and the impartial witness, where applicable.”

The NHG DSRB SOP also specifies that, “The information provided in the consent documents must be in a language understandable to the subject. The consent document should not include complex language that would not be understandable to subjects. Technical and scientific terms should be adequately explained using common or lay terminology.”

In other words, the Participant Information Sheet must be developed in such a way that it meets the literacy level of the study population.

Literacy Level in Singapore

Based on data from the 2010 Singapore Census, the literacy rate in Singapore is about 96% for population aged 15 years and above. About 68% of the population are educated beyond secondary school level, while 32% are educated up till primary school level.

Those aged between 25 to 39 years are the most highly educated, with 92% having secondary level education and above. On the other spectrum, about 70% of those aged 55 years and above, and 37% of those aged 45 to 55 years, have an education level that is below that of secondary school.

Some international research suggests that the readability of such documents should ideally be one to two standards below the reading literacy of the reader. In addition to developing a good Participant Information Sheet, the investigator should also ensure that the information contained therein is properly explained to the subject in a manner that the subject is able to understand.

Making the Participant Information Sheet Simpler

There are online medical dictionaries that investigators may use to translate medical and scientific terms into layman terms. A medical term such as “hepatocellular carcinoma” can be simply explained as “a tumour of the liver”. A good website that you may use is Mondofacto online medical dictionary (www.mondofacto.com/dictionary).

In addition, there are free online software and websites that allow you to calculate or estimate the readability of your document. The Flesch- Kincaid Grade readability test is one such example. It is used to analyze and rate the readability of text based on the United States grade school level. The score is calculated based on an average number of syllables per word and words per sentence. A score of 8.0 would mean that the average eighth-grader will be able to understand the text.

Here are some websites that investigators may use to rate the readability of the participant information sheet:

- www.onlineutility.org/english/readability_test_and_improve.jsp
- www.office.microsoft.com/en-us/word-help/test-your-document-s-readability-HP010148506.aspx
- www.harrymclaughlin.com/SMO.htm

Investigators may also consider having a layperson review the consent document first to assess the readability and comprehensibility of the information to the target population.

QUESTION 1
Is the document written at a reading level understandable to research subjects?

QUESTION 2
Is the document formatted well? Does it have headings which break the text into short sections?

QUESTION 3
Can the document be shortened without compromising clarity or other requirements?

Guidelines from National Institutes of Health

The U.S. National Institutes of Health, Office of Human Subject Research provides a good guide on writing consent documents. Below are some questions that investigators should ask themselves when writing or reviewing a participant information sheet.

Usually, before a subject agrees to participate in a research study, he/she not only reads a written consent document but also discusses the study

with a researcher. A suggestion when writing consent documents is to assume that prospective subjects will not talk to a researcher (or research nurse) at all about the study, and that all their information will come entirely from the consent document. If this approach is used, the document is more likely to be clear, complete, devoid of medical/scientific terminology and able to "stand alone".

More information may be viewed at ohsr.od.nih.gov/info/sheet6.html.

Resources:

- i. NHG Investigator Manual - All That An Investigator Needs to Know
- ii. Participant Information Sheet Checklist (Page 128 -131) (Available at the NHG Research Portal www.research.nhg.com.sg -> Resources -> Research Online Guidebooks)
- iii. NHG PCR SOP - 501-C01 Informed Consent Document and Process Final. (www.research.nhg.com.sg) -> Resources -> Research SOPs)

References:

- SGGCP – Section 4.8.6
- National Institutes of Health, Office of Human Subject Research (<http://ohsr.od.nih.gov/info/sheet6.html>)
- www.singstat.gov.sg/stats/charts/lit-edu.html

THE PRINCIPAL

INVESTIGATOR'S ROLES & RESPONSIBILITIES

No.5: Communicate with Regulatory Agencies and obtain approval to conduct study

Obtaining DSRB and HSA Approval

Before initiating a research study involving human subjects, the Principal Investigator (PI) should obtain the written and dated approval from the NHG Domain-Specific Review Boards (DSRB). In general, approval from the DSRB is valid for a period of one year. For the conduct of clinical trials, approval from the Health Sciences Authority (HSA) is required and is issued in the form of a Clinical Trial Certificate (CTC). Each CTC is valid for a period of two years unless otherwise stated.

Documents For Approval & Ongoing Review

Documents that are to be submitted for approval include the study protocol, written informed consent form, consent form updates, subject recruitment procedures advertisements and any other information to be provided to subjects (e.g. written Documents that are to be submitted for ongoing review

include protocol amendments, adverse events, non-compliance, deviations, or new information about the study). No deviation or changes to the protocol should be implemented without the documented approval from the DSRB, except where necessary to eliminate an immediate hazard(s) to study subjects.

Submitting Status Updates

Regular status updates should also be provided to the DSRB and HSA. The DSRB requires a status report form to be submitted annually, at least 30 days before the approval expires. When a study is completed, the PI should submit a study completion report (using the status report form) within 30 days after completing the study. When a study is suspended or terminated by the institution, PI or the sponsor, the PI should submit a report within 7 days. The HSA requires a 6-monthly report to be submitted from the date of approval. If the trial is expected to continue

beyond the 2-year approval period, the Sponsor (or PI for PI- initiated studies) should apply to HSA for renewal 3 months before the approval expires.

Other Changes Requiring DSRB Approval

If the PI is resigning from the institution or is going away for an extended period of time, the research project should be formally transferred to another Investigator. This Investigator assumes all the responsibilities as the PI for the conduct of the research project until the original PI returns. This change should be reviewed and approved by the DSRB. Any other changes to the study team should also be reported to the DSRB.

References:

- Singapore Guidelines to Good Clinical Practice Section 4.4
- Investigator's Manual Chapter 4 Submissions to DSRB
- Health Sciences Authority Guidelines for Clinical Trials

No.6: Assure Protocol Compliance throughout study



Protocol Compliance

The investigator or institution maintains protocol compliance by agreeing to conduct the trial in accordance with the approved protocol agreed to by the sponsor and, if required, by the regulatory authority and which was given approval by the relevant institutional review board (IRB), or the Domain-Specific Review Boards (DSRB).

Assuring Protocol Compliance

The PI should assess the feasibility of the protocol and ensure that there are adequate resources (e.g. manpower) and time to conduct the trial so that the protocol may be carried out reasonably to ensure protocol compliance. The inclusion and exclusion criteria of the study need to be determined if they are applicable to the study population as well.

The PI should also put in place realistic and attainable recruitment targets, be thoroughly well-versed with the protocol requirements, and adhere to the trial procedures so as to assure protocol compliance.

To ensure compliance, the PI may employ practical measures such as:-

- using an eligibility checklist for screening or enrolling subjects,
- reviewing the inclusion and exclusion criteria, visit schedules, study end-point criteria,
- training the research team on investigational product use (if applicable),
- training new study team members adequately.

Protocol Deviation

A protocol deviation occurs when the PI or study team deviates from the procedures or requirements stipulated in the protocol. No deviation or change to the protocol should be implemented without prior agreement by the sponsor and approval by the DSRB, except where necessary to eliminate immediate harm or hazard to the participant, or if it involves administrative changes to the research study.

Noncompliance

A noncompliance occurs when the PI fails to conduct a study as explicitly described in the protocol, whether by accident, on purpose, or due to negligence.

Reporting of Noncompliance and/or Protocol Deviation

The PI should report any occurrence of noncompliance to the DSRB via the DSRB Noncompliance/Protocol Deviation Event Report Form. A non-study team member may also report the noncompliance to the DSRB.

In this case, the confidentiality of the reporter will be protected unless a disclosure is required. If the allegation is determined to be valid, the investigator will be required to give an explanation and provide a corrective action plan to avoid repeating the noncompliance.

For serious or continuing noncompliance, the DSRB will notify the Department and Institution Representatives, Health Science Authority (HSA) and the Sponsor. Other relevant authorities such as the Research Ethics Committee (REC), Food and Drug Administration (FDA) or OHRP (Office of Human Research Protection) may also be notified. Punitive actions may be taken by the institution, and the DSRB must be kept informed.

When should the non-compliance be reported?

The investigator should document a non-compliance occurrence and explain the deviation in an event reporting form to the DSRB within 7 calendar days. The sponsor should be notified as soon as possible.

References:

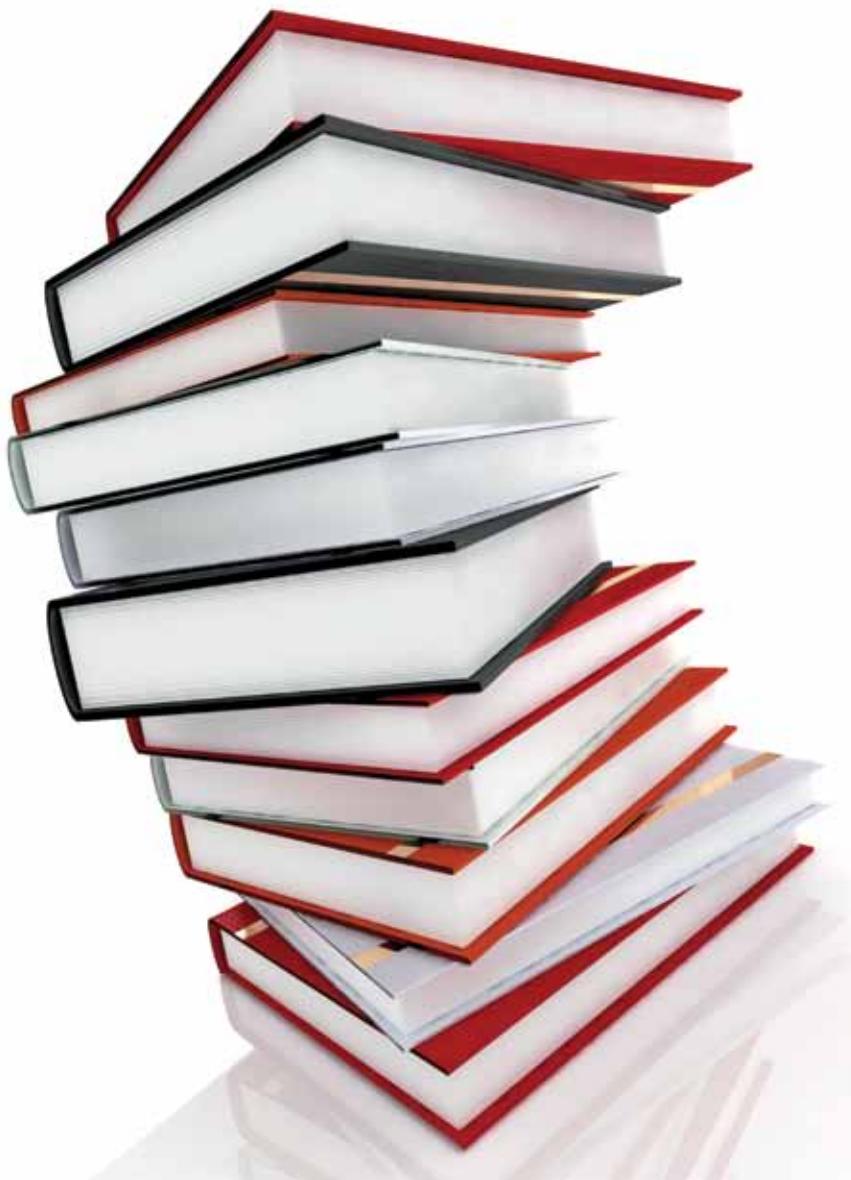
- SG GCP : Investigator – Compliance with Protocol www.gcpdesk.com/index.php/knowledge-base/item/download/6
- NHG PCR SOP 501-A02 Responsibilities of Investigators www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+sops

“I am proud to say that I am now a C.C.R.P. (Certified Clinical Research Professional). This certification has definitely boosted my confidence and enabled me to perform better in my area of work. I certainly hope that many more will join me in achieving international certification in the clinical research field.”

SoCRA C.C.R.P. CERTIFICATION EXAM

How it Improved My Career and Knowledge

Jac Ang
Assistant Coordinator
DSRB Domain B
National Healthcare Group



“Having no prior experience in conducting clinical research can be very daunting, especially when you are in contact with patients and are required to perform research-related procedures. I still remember when I first embarked on my journey in clinical research in 2006, enrolling in the only course available which was the Singapore Guideline for Good Clinical Practice (SG-GCP) organized by National University of Singapore (NUS). With more courses now available, it has certainly helped improve the standards and knowledge of Clinical Research Professionals (CRPs).

The Certification in Clinical Research Professional (C.C.R.P) issued by SoCRA (Society of Clinical Research Associates) is one of the professional certification available for CRP who wish to demonstrate their competency and knowledge in the clinical research arena. It is an opportunity for anyone who is involved in any aspect of clinical trials to gain international recognition as well as to broaden their knowledge through the resources made available by SoCRA.

I was given the opportunity to sit for the SoCRA CCRP Certification exam in June 2009 hosted by National Healthcare Group (NHG) Research & Development Office (RDO) and was among the 27 CRPs who took the inaugural exam. The study guide book provided by SoCRA was self-explanatory and was made available at least 6 weeks before the exam upon successful registration.

My experience in taking the SoCRA CCRP Certification exam was a mind-stimulating one. Even though the questions were straight-forward and easily understood, it took me 3 hours to complete the 135 multiple choice questions and left me with just enough time to check through my answers once. ”

NHG RDO will be hosting the next C.C.R.P. exam on 8-9 March 2012. There will be an exam preparatory workshop for interested candidates too!

For enquiries on the SoCRA C.C.R.P. Exam, please kindly contact NHG RDO at researchcoord@nhg.com.sg



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