

the bellberry community

12.09

supporting research and ethics

Volume 1 Issue 1
December 2009

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FROM THE CEO

WELCOME TO THE INAUGURAL NEWSLETTER OF BELLBERRY LIMITED - BELLBERRY COMMUNITY.

Since Bellberry commenced operation in July 2004, we have grown to become a valued and recognised provider of human research ethics review across Australia. From 12 meetings in 2005, we should finish this year having held 37 meetings and we anticipate further growth in the year ahead.

Earlier this year the Bellberry Board held a strategic planning day to consolidate plans for the next two years. Key outcomes included:

- Agreement that the provision of safe, high quality Human Research Ethics Committees (HRECs) ensuring the safety of research participants' remains the focus
- The introduction of a third committee in 09/10 to provide more meetings to cope with growing demand, increase flexibility and help facilitate the rapid turnaround of clinical trial review
- Commitment to enhance our IT capability to better support our current operations and prepare for future growth
- Ongoing effort towards meeting all relevant standards used in the USA and UK in the absence of recognised standards for the accreditation of HRECs in Australia
- Acknowledgement of the need to increase the focus on training and education of committee members, as being vitally important to our operations
- Ongoing commitment to donating surplus funds to the health research community.

We will continue to look at other ways to improve our service delivery and the introduction of this newsletter is just one of the ways we will help keep our community up to date with our activities.

Please don't forget to visit our website at www.bellberry.com.au for all submission requirements, meeting dates and other information.

Feedback on the newsletter, website and all elements of our service is also welcome and we look forward to hearing from you in the future.

My very best wishes for a merry Christmas and a safe and happy New Year.

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CATHY STEVENS, COMMITTEE MANAGER
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INCREASING OUR FOCUS ON QUALITY

Bellberry recognises the importance of quality systems and processes to help ensure our committees comply with relevant legislation, guidelines and policies and provide a seamless and consistent service to our customers. We therefore invest significant time, energy and resources in policy and procedure development and training.

With the growth of our committees, the importance of consistent decision making and compliance with our policies and procedures by all the committees becomes more paramount.

In recognition of the importance of this task, Ms Cathy Stevens was appointed as Committee Manager in August 2009, responsible for the effective coordination, function and management of our committees.

This role, in conjunction with the Committee Chairs, is also responsible for consistency of training, policy and decisions in our committees, along with communications between the committees to ensure we provide the highest standards of human research ethics reviews.

Please do not hesitate to contact **Cathy** if you have any concerns or queries regarding our committees functions.

BB **NEED AN HREC URGENTLY!**

Bb Bellberry HRECs hold more meetings than any other committee in Australia and we ARE national!

bB

bb Contact Imelda Lynch CEO if your requirements are more urgent than the dates posted.
imeldalynch@bellberry.com.au

WELCOME TO OUR 3RD HUMAN RESEARCH ETHICS COMMITTEE

To cater for steadily increasing demand, in November, the first meeting of Committee C was held. We will now hold three regular meetings per month and will call an extra meeting as necessary. Meeting dates are available at www.bellberry.com.au

Our Committees are ably chaired by Professor Brian Stoffell (Committee A), Ms Yvette Winter (Committee B) and Dr Michael James (Committee C).

We are now working hard toward constituting a fourth committee. Once we have achieved this we will post four regular meeting dates per month and will continue to call an extra meeting when required.

EDUCATION SESSIONS

This year, two education sessions were held for Committee Members.

Professor Colin Thomson, the then Chair of the Australian Health Ethics Committee provided a wonderful session titled 'Human Research Ethics in Australia, where we've been, where we are (and why) and where we might go'. Thirty four Bellberry Committee members attended the evening and found the talk extremely informative and interesting.

Erwin Deutsch, Professor at Law, from Goettingen University Germany also mesmerised us all with his presentation titled 'Clinical Trial Disasters'. Professor Deutsch used his worldwide knowledge to highlight the potential pitfalls of clinical trials citing examples of disasters that had occurred in the past.

A number of committee members have also attended Ethics Centre of SA workshops and presentations and we are pleased to support the attendance of two members at the Monash Intensive Research Course in November this year.

COMMITMENT TO REDUCING OUR TURN AROUND TIMES

Timeliness is also critical to our operations as we are aware that delays to review and feedback can be costly.

The following graph represents the results of an internal quality review conducted by our committee manager. We are working towards reducing the 15 day timeline where a study is received prior to its review by a committee.

We believe that ideally this should be a minimum of ten days but hope with the introduction of our new software this may decrease even further.



SITE MONITORING

One of our responsibilities under the National Statement on Ethical Conduct in Human Research 2007 (Chapter 5.5 'Monitoring Approved Research') requires Bellberry to monitor and report on sites undertaking research that we approve for trials.

Unlike institution based HRECs, Bellberry does not have the benefit of investigators being located on site. We are very aware of our responsibility to ensure that the same level of site monitoring and review occurs as if we were based on site.

To assist us in this process, Bellberry contracts Research Management Systems (RMS) to conduct site monitoring on our behalf. Individual sites are contacted initially by Bellberry to provide the referral to RMS. Catherine May from RMS then liaises with individual sites to ensure visit dates and times are mutually acceptable to both parties.

Catherine reports as per the National Statement and the reports are tabled at the relevant committee meeting with any required action recommended to the Principal Investigator. Catherine also assists our sites by letting us know any issues, problems or suggestions sites may have for us on better ways to improve our service.

HARMONISATION OF MULTICENTRE ETHICAL REVIEW (HoMER)

As most of you would be aware, the Harmonisation of Multi-Centre Ethical Review (HoMER) enabling system stemmed from discussions held in 2006 for an inter-jurisdictional working party to be established. The role of the working party is to advise the Australian Health Ministers Advisory Council (AHMAC) with the aim of streamlining multicentre ethical review of medical and health research across Australia.

As the project has progressed, there has been a slight shift in the focus from the development of a national system to the development of national tools. The project remains committed to the provision of common policies and standardised forms and processes.

As we have done so for the past five years, we continue to provide single review of multi centre research across Australia within the private sector. We have been closely involved in the HoMER process and intend to nominate to be part of the national system. We hope the outcome is favourable to all involved and in particular the efficiencies gained through single review of multi centre research are realised in all sectors.

EPROTOCOL INFORMATION TECHNOLOGY – MAKING OUR PROCESSES EASIER FOR ALL

Following an in depth review of software to manage ethics review functions, a contract has been signed with Key Solutions Inc, California to provide the eProtocol software for the management of our committee functions.

This system, which should be in place by early 2010 will enable:

- all submissions to be made on line
- researchers to track the process of their application at all times
- committee members to communicate with each other outside of meetings
- improved efficiencies in generating and tracking committee minutes and correspondence.

It is hoped that the investment in this software will speed up processes and increase our capacity to manage more submissions as well as reduce the many frustrations associated with current paper based submissions.

The eProtocol system will be accessed via the Bellberry website which is being upgraded along with the eProtocol introduction.

WANT TO STREAMLINE YOUR SUBMISSION EVEN MORE?

Ring or email Bellberry today to book your spot on an agenda!
 08 8361 3222 • bellberry@bellberry.com.au • www.bellberry.com.au

COMMITTEE MEMBER PROFILE

Bellberry has a core group of dedicated committee members drawn from hospitals, universities and the local community. Each committee's medical/science membership varies depending on the expertise required to review the studies at hand. We also have extraordinary support from external advisors who provide expert opinion when needed.

I thank them for their expertise, commitment and support and look forward to their ongoing input as we continue to build and improve our services to our customers.

In this newsletter we introduce



ANDREW ALSTON

Andrew, one of four lawyers who sit on our committees, has been a member since Bellberry's inception in 2004.

As a member of the Bellberry Policy Committee, he has provided integral input into the development of our standard policies and procedures. Among Andrew's publications is a play 'Ethical Dilemmas', which he designed as a teaching exercise on ethical problems facing lawyers, company executives, researchers and doctors. It is soon to be produced as an animated feature. Away from work, Andrew plays the baritone saxophone, which he took up following a failed career as a hockey goal keeper.

STAFF PROFILE

CHERYLYN HART COMMITTEE SECRETARY



The committee functions continue to be ably managed by Cherilyn Hart, Committee Coordinator.

Since joining Bellberry in July 2005, Cherilyn has taken on extra responsibility and has been integral to the success of the company and taken the growth in her stride. Always cheerful, she goes above and beyond to provide an efficient and effective service. Cherilyn's ability to sprout out the protocol numbers of any trial also leaves others in the office astounded.

Away from work Cherilyn is an avid skier who is familiar with most ski slopes in Australia, New Zealand and Japan. Cherilyn is very much looking forward to skiing in Whistler in March next year.

Contact Cherilyn
P 08 8361 3222
bellberry@bellberry.com.au

DONATIONS

The Board remains committed to the ongoing donation of surplus funds to Medical Research and we are extremely proud of the relationships we have been able to build through our University donations and the development of Bellberry scholarships

Bellberry is proud to offer this not for profit company model as an efficient and effective service to support the excellent research community within Australia.

Please visit our website for more donation information www.bellberry.com.au

FEEDBACK

LET US KNOW WHAT YOU THINK ABOUT OUR FIRST NEWSLETTER

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