AAHR NEWS 110
September 2006

Australian Association for Humane Research Inc.

Patron: Professor John Coetzee

AIMS OF THE AUSTRALIAN ASSOCIATION FOR HUMANE RESEARCH INC.

- *To promote all viable methods of healing which do not at any stage involve the use of animals.*
- *To promote the use of scientific alternatives in all forms of medical, scientific and commercial research.*
- *To help disseminate evidence, as it becomes available, that the use of alternatives is less costly, more accurate and more humane than the use of animals in experiments.*
- *To work for the abolition of all experiments using animals.*

Welcome

Well, despite our best efforts to keep this newsletter a little shorter this time, with two major campaigns launched, our Annual General Meeting to report on and our "Focus On…" article about clinical research, it was just far too difficult to hold anything over until next quarter! Besides, I'm sure our next newsletter will have just as much news to report anyway.
So, while you are provided with a little extra reading matter, I do hope you will find it both inspirational and informative.

Until then,
Helen Rosser

Mind Body Spirit

A special note to say 'thank you' to all those members who visited our booth at the Mind Body Spirit Festival in Melbourne recently. It was really wonderful to put faces to names. We were absolutely overwhelmed with the level of interest shown to AAHR and we have already signed up again for next year's festival. So if we missed you this time, we hope to see you next year!

New AAHR Merchandise

We are planning on having our new merchandise available in a couple of months, so look out for our new exciting t-shirts and stickers. Don't forget, any profit from our sales of merchandise goes directly towards supporting the vital work we do. Further information will follow soon and if you're looking for a Christmas gift, please keep us in mind!

Membership Raffle

Congratulations to Susan Pasmik of Granville, NSW, who is the winner of our membership raffle. Susan has received a $50 gift basket of vegan and cruelty free goodies from the Cruelty Free Shop (www.crueltyfreeshop.com.au).

Thank you to all who have renewed, and if you haven't yet, please do so soon – we need you!

Upcoming Expos

AAHR will be participating in the following events so please call in to say hello if you are attending.

Melbourne's Cruelty Free Lifestyle Expo
Sunday 8th October, 10am-5pm
Prahran Town Hall
www.livecrueltyfree.org

Melbourne's Vegan Picnic Day
Sunday 29th October 10am
Phoenix Community Reserve,
East Malvern.
www.worldveganday.org.au

Sydney's Cruelty Free Living Festival
Sunday 5th November, 10am – 4pm
Petersham Town Hall, 107 Crystal Street, Petersham
www.crueltyfreefestival.org.au

New email and website addresses

Our email and website addresses have been changed to fall in line with standard addresses. It appeared that many people had been unable to find our website due to our unusual extension (.asn). Our new addresses are:
Email: info@aahr.org.au
Website: www.aahr.org.au

Our previous addresses will remain active during a phase out period but please amend your records to reflect the new ones.

Don't forget to visit our website on a regular basis as we are always adding new campaigns, articles and press releases.

Suite 234, Toorak Corporate Centre
29 Milton Parade, Malvern, Vic. 3144
ABN: 87 529 064 573

Phone: (03) 9832 0752 • Fax: (03) 9832 0753
Email: info@aahr.org.au • Web: www.aahr.org.au

Fetal Calf Serum

As a lot of you would be aware, at Australian Association for Humane Research our strong view is that the use of human cell and tissue culture is clearly a more ethical and scientifically-valid mode of research than using animals. Unfortunately though, even when using these "in-vitro" methods, a component of animal cruelty can possibly still remain.

Human cells and tissue are grown in a culture form, and in order for the cells or tissue to grow and proliferate, a source of nutrients, namely hormones and growth factors must be added. The usual supplement is fetal calf serum – a product that is cruelly derived from the fetuses of cows found pregnant at slaughter. Serum is blood without any cells, platelets or clotting factors and fetal calf serum especially, is considered to be a rich source of nutrients.

Method of collection:

After slaughter and bleeding of the cow at an abattoir, the mother's uterus containing the calf fetus is removed during the evisceration process (removal of the mother's internal organs) and transferred to the blood collection room.[1] A needle is then inserted between the fetus's ribs directly into its heart and the blood is vacuumed into a sterile collection bag. Only fetuses over the age of three months are used otherwise the heart is considered too small to puncture.[2]

Once collected, the blood is allowed to clot at room temperature and the serum separated through a process known as refrigerated centrifugation.

It remains questionable as to whether or not fetuses have already died from anoxia (deprivation of oxygen) prior to serum collection. Nevertheless, no anaesthesia is given, despite their possible ability to experience pain and discomfort.

Disadvantages of using FCS:

While of course we don't advocate cruelty to any living being, there are many compelling scientific reasons why Fetal Calf Serum should no longer be used in research. Here are a few strong arguments:

- Serum is a major source of viral contaminants which once present, are almost impossible to remove from cultures. It can contain viruses, prions (a protein that can transform into a rogue agent) and mycoplasma (considered to be a primitive form of bacteria),[3] each of which can skew the outcome of scientific experiments.
- Many substances present in FCS have not yet been identified, and of the substances which have been, the function of the cultured cells is not always clear."[4]
- FCS can interfere with genotypic and phenotypic cell stability, which can also influence experimental outcome.
- Serum can suppress cell spreading, attachment and embryonal tissue differentiation, which is the process by which embryonic cells develop into specialized cells for particular functions. Critically, this can actually prevent an objective of cell growth research especially when we talk about growing new organs and limbs.

Alternatives:

Rather than just criticizing a process of research that uses animals, our objective at AAHR is always to present realistic and viable scientific alternatives. In this case, like all, a number of alternatives to the usage of FCS do actually exist !

- 'Focus on Alternatives' is a group of British organizations working together to advance the replacement of animal experiments. It has compiled a document called "Serum-free media for cell culture" which provides an overview of the range of commercially available serum-free media.
- Similarly, Zet, The Centre for Alternative and Complementary Methods to Animal Testing, in Austria has compiled the "Serum Free Cell Culture Media Updated Product Guide 1/2004-05,"

Copies of all of these documents are available from AAHR.

- Australian company Tissue Therapies Limited has been working hard to produce objective data proving that its synthetic VitroGro® protein complex can replace all animal proteins, not just calf serum, for the culture of a range of different cell types. TTL estimates that commercial supply should begin in small volumes late in 2007.

What can you do?

- If you are directly involved in research and require sera, consider the use of an alternative to FCS.
- If you are a member of an animal ethics committee, insist that an alternative to FCS is used.

(Footnotes)

[1] Personal correspondence with AQIS Meat Operations.

[2] Carlo E A Jochems, Jan B.F. van der Valk, Frans R Stafleu and Vera Baumans. 2002. "The use of fetal bovine serum: ethical or scientific problem?" Alternatives to Laboratory Animals (ATLA) 30, 219-227.

[3] E. Falkner, H. Appl, C. Eder, K. Macfelda, U. Losert, H. Schoeffl, W. Pfaller,. "Serum Free Cell Culture Media Updated Product Guide 1/2004-05," Zet, Centre for Alternative and Complementary Methods to Animal Testing, Austria.

[4] Carlo E A Jochems, Jan B.F. van der Valk, Frans R Stafleu and Vera Baumans. 2002. "The use of fetal bovine serum: ethical or scientific problem?" Alternatives to Laboratory Animals (ATLA) 30, 219-227.

Clinical Research

Clinical research has attracted a great deal of media attention since the recent UK drug fiasco (see newsletter 109), but what exactly is a clinical trial? Dr Lisa Askie, Manager of the Australian Clinical Trials Register at NHMRC Clinical Trials Centre explains as follows.

What is a clinical trial and what is its role in the development of drugs and treatments?

Clinical trials are research studies that involve humans. They test the effect of interventions. Interventions can be drugs or treatments but can also be other things such as surgical procedures, ways of diagnosing illness, educational methods, lifestyle changes or new technologies or devices. In many cases, particularly when testing new drugs, clinical trials involving people begin only after laboratory and animal studies of the intervention have shown promising results and the intervention's 'safety' has been established. Once a new intervention has been proven to be safe and effective it may become the new standard treatment.

Many clinical trials, particularly those involving new drugs, move through steps, called **phases**. Each phase is designed to ask and answer specific questions in a way that provides reliable information to researchers while protecting the participants. A new intervention must successfully pass through one testing phase before moving on to the next. But testing can be stopped at any time in any phase in order to ensure the safety of the participants. There are three major phases of the clinical trials process that usually occur before a new treatment or drug is licensed, and a fourth phase that may be included after the product is on the market.

What does it actually entail for the volunteers?

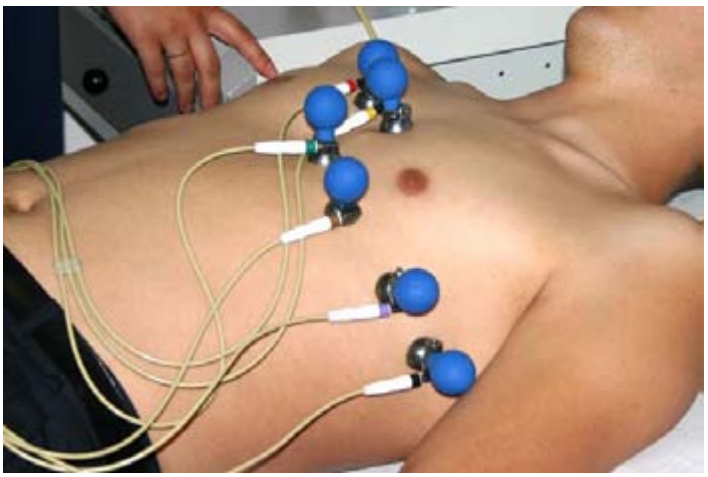
People who agree to participate in a clinical trial are allocated to receive either a new (sometimes called 'experimental') treatment or an alternate treatment. The alternate treatment can either be the current standard treatment or, if there is no usual treatment, they might receive a 'placebo' which is an inactive version of the new treatment (for example, a sugar pill that looks exactly the same as the new pill). If the volunteers are participating in a 'randomised' trial, then the way they are allocated to a treatment group is done 'at random'. For example, the researchers might toss a coin to decide whether the volunteer will receive the new treatment or the standard treatment. 'Random' allocation is the only fair way of ensuring that the groups of people being compared are as similar as possible at the start of the study. In this way there can be a comparison of 'like with like' and thus any differences seen in people's health at the end of the study can be attributed to the new treatment.[1]

Once volunteers are allocated to different groups and given the different treatments, they are followed over time and certain 'outcomes' are assessed. Outcomes might include things such as: how long it took for a cancer to relapse, was knee pain reduced, did participants stop smoking during pregnancy. These trial 'results' are then analysed to see if there were any significant differences between the outcomes in each group (more than one would expect just by chance) which could be attributed to the new treatment.

What types of risks are involved for volunteers?

There are always some risks involved in volunteering to test new treatments. The important issue is having those risks fully explained and being able to make a free choice as to whether to participate in the trial or not. This is known as 'informed consent'. Many people volunteer to participate in clinical trials for altruistic reasons, i.e. they are prepared to take the (usually small) risk of being harmed themselves if this means that future patients will benefit from the advances in medical care that the trial will discover.

In clinical trials there are several safeguards that are put in place to minimise the risks to volunteers. Apart from informed consent, participants always have the right to withdraw at any time without fear that their normal health care will be jeopardised.



Before anyone can be enrolled in a clinical trial, the details of how the trial will be conducted (the trial protocol) are reviewed and approved by an independent group of people who check that it will be carried out in an ethical way. These groups are known as Ethics Committees or Institutional Review Boards (IRBs). These boards or committees are usually derived from a wide source of community vocations and can include those who are not doctors or researchers, as well as lawyers and even ministers of religion or community elders.

Once underway, many trials have another independent group of people who assess the trial's conduct and results as it progresses to ensure it is being conducted properly and that the participants are not being exposed to unnecessary harm. These groups are known as Data and Safety Monitoring Committees or Boards and include people who have no direct involvement in the trial but who generally know what harm to expect and understand how to interpret the results as they come through. The background of people on these boards will generally be from the medical profession.

If tests are already conducted on animals why is it therefore necessary to test on people?

Whilst testing in the laboratory and on animals (the pre-clinical phase) are important parts of the development of new medicinal products, it is ultimately necessary to test whether new products work as predicted in humans as human physiology is different to animals. Human testing is usually conducted in a staged manner, in different phases, as described previously. This enables a safe and optimal dose to be established first, in very controlled circumstances. The new product is then tested on large numbers of people in 'real world' situations to see if it is effective in producing the health benefits it was designed to achieve.

It's been estimated that about 85-90% of drugs that reach clinical trial fail to reach general distribution. Is this true?

Registration of clinical trials on the Australian Clinical Trials registry (ACTR) is currently voluntary. As such, people conducting clinical trials are encouraged, but not required, to register their trial. Thus, from our data we are unable to estimate the proportion of early phase trials that fail to eventually get to market. Should registration of all clinical trials (including early phase trials) be made mandatory, as recommended by the World Health Organisation, we would be able to answer this question more accurately using the ACTR data.

Can you comment on why things may have gone wrong in the UK TGN1412 trial and what is the likelihood of something similar happening here?

The TGN1412 trial was conducted in accordance with a protocol approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA). However, there has been some criticism of the fact that all the trial participants were given the drug at the same time. The UK Academy of Medical Sciences subsequently published a position paper (located at www.acmedsci.ac.uk) that stated "It would be usual practice to administer a single dose in a single patient, who would then be observed for an appropriate period of time." Following the incident earlier this year, the MHRA has set up a group of leading international experts to review the case and consider whether changes to clinical trials' (particularly Phase I trials) procedure are necessary.

The tragedy of this trial has sparked renewed calls for a more open and transparent culture in medical research.[2,3] Had the trial protocol be made available for public review, potential problems may have been identified and avoided. Over the past few years calls have increased for the disclosure of key aspects of clinical trials in publicly accessible trial registers, prior to the enrolment of participants. The ACTR has helped Australian researchers in this endeavour by providing a place where they can register information about their trials before they start treating participants. The ACTR can be accessed and searched free of charge. Its website is www.actr.org.au.

Further information about clinical trials can been seen at:
http://www.trialscentral.org/faq.htm#Whatareclinicaltrials

1. Evans I, Thornton H, Chalmers I. Testing treatments. Better research for better healthcare. 1st ed 2006. British Library: London.
2. Goodyear M. Learning from the TGN1412 trial. This experience should foster an open culture in medical research. BMJ 2006;332:677-8.
3. Gregory A. Northwick Park reactions. MJA 2006;184(8): 417.

Annual General Meeting

The Annual General Meeting of AAHR was held on Saturday 26 August.

Anyone wishing to receive a full copy of the Annual Report, including financial statements, or a copy of the new constitution, can obtain either by contacting our office on (03) 9832 0752 or email info@aahr.org.au.

We are pleased to advise the following people were re-elected to the management committee for 2006/2007:

President:	Mrs Steph Geddes
Vice President:	Mrs Elizabeth Jackson
Honorary Treasurer:	Mr Miles O'Connor
Honorary Secretary:	Mr Brian Gardiner
Committee members:	Mrs Jenny Fairless
	Mrs Sarah Gardiner
	Mr Barrie Cooper

MAWA

One of the constitutional changes carried at the AGM was the deletion of clause 2f [The Australian Association for Humane Research Inc. also acts as the Trustee of the MAWA (Medical Advances Without Animals) Trust].

At the MAWA Annual General Meeting held on 13 December 2005, there was agreement in principle amongst those present that MAWA should function as a separate entity from AAHR.

One of the major purposes of the MAWA Trust is to encourage scientists to use the growing range of non-animal methodologies which are available and to build a bridge with those who are genuinely concerned with the plight of laboratory animals.

To this end it is felt that the Trust should be seen to be run by scientists and that the trustees should not have any open connection with the animal rights/animal welfare movement.

The new trustees will therefore be Ms Elizabeth Ahlston, Dr Anne Keogh and the Hon. Kevin Rozzoli.

The new administrators of the Trust will be Sharyn Watson Kidd and Raymond Kidd.

The new postal address for MAWA will be:

PO Box 4203
Weston Creek
ACT 2611

If any members have any questions or concerns about the AAHR / MAWA separation, please feel free to contact our office to discuss further.

Say “NO”... to Dissection.

If you are a science student in Australia, chances are you will be told at some point to dissect a preserved animal specimen in biology class at high school. If you go on to study biology, zoology, vet science, medicine, psychology or a range of other science subjects at university there will be more to come, including live animal experimentation. Do you really want to?

More and more students, teachers and parents are turning away from dissection – and for excellent reasons.

What’s wrong with dissection?

It causes animal suffering and death

Every year in Australia, thousands of animals are killed in school, college and university courses. Rats, mice, cats, dogs, pigs, chickens, frogs, toads and fish are amongst those most commonly used. Most are killed and dissected (cut apart). Others are vivisected (subjected to an invasive procedure whilst still alive), or used in experiments involving harm and/or death.

It devalues life

Dissection teaches that animals are throwaway objects. It teaches a profound disrespect for the life it aims to study. Many smart and caring students decide not to pursue careers in medicine, or nursing when they find out they are supposed to dissect animals. Dissection may be turning students away from professions where they are needed the most.

Some animals are specifically raised for dissection which contributes to a loss of lives. Even the use of animal parts from slaughterhouses, where animals have been killed for another purpose is based on the assumption that an animal’s life is expendable, and has no value except for human exploitation.

It is a waste of money

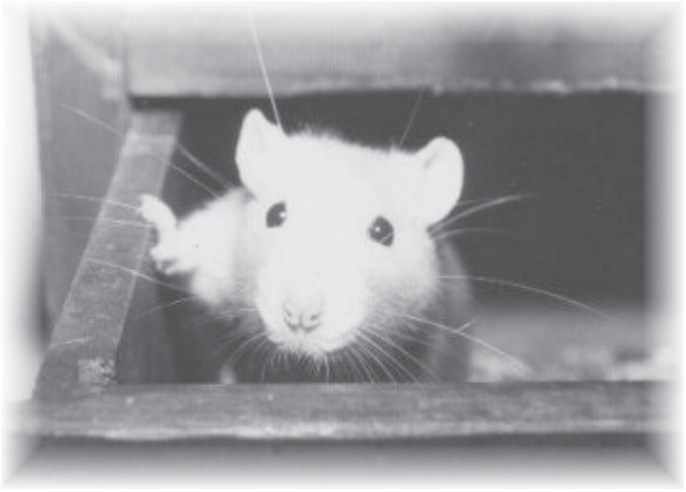
Dissection has a built-in economic problem - you can dissect an animal only once. Alternatives such as computer simulations on CD-ROM, 3-D Models and videotapes can be used over and over again. These materials, within a year or two will pay for themselves. For the average school or university, replacing dissection with alternatives can end up saving thousands of dollars.

It is not the best way to learn

More than 25 published studies confirm that those students using alternatives learn as well or better than students who use animals. This is not surprising: alternative exercises can be repeated and show the continuous processes of life, such as how a heart beats that dissection cannot. Ask your average teacher who will tell you that students spend more time playing around, joking and trying to ‘gross’ one another out during dissection than actually learning anything.

It is outdated

Dissection was introduced in the 1920’s. Since then, more sophisticated tools have been introduced which provide a better learning experience, cost less and do not kill animals!



What can you do?

If you are a biology student, ask your teacher or lecturer what the class requirements will be. If animal dissection or experimentation is part of the course, is it optional? Explain politely and firmly why you would like to do an alternative project. Be clear, be positive, and be respectful. The biggest problem your teacher may have with your request is not knowing what alternative to provide.

Offer to provide one - contact AAHR for information on the Humane Education Loan Program (HELP), or give your teacher or lecturer the details. The Humane Education Loan Program is a free loan program to provide students and educators with up to date alternatives to classroom animal dissection and animal experimentation.

If your teacher refuses to grant your request for an alternative, seek support. Your parents may be willing to help out, or alternatively contact AAHR for advice. You may need to submit an information packet to the school or college. University students can talk to the Animal Welfare Officer and if there isn’t one, find out why. If you are still not getting a response, apply pressure with perhaps a student petition and publicity.

Convince your school to adopt an official policy requiring teachers or lecturers to offer alternatives to dissection and animal experimentation. You may even get them eliminated altogether! Many schools and universities have taken these steps. Keep us updated on your progress and let us know when the policy is in place.

- Work together with other students who want humane alternatives.
- Write letters to your local newspapers and school and university newspapers, and meet with your Principal or Dean.
- Write a letter to your Minister for Education.
- Contact us if you need advice.

Check our dissection campaign page on our website for help on drafting an official policy, letters to teachers and newspapers, and for a current list of State Education Minister’s contact details.

The above information and the Humane Education Loan Program has been kindly donated to us by HSI Australia . The program was originally funded by Hans Walloschek. We thank them both for their generosity.

RETARDED RESEARCH

Some folk will try to tell you that to cure our human ills,
To find a cure for cancer or to test arthritis pills,
We need to do our testing, on mice and dogs and cats,
And other little animals like guinea pigs and rats.

Well this is simply quite untrue as very soon you'll see,
'Cos what is safe for them to eat could poison you and me.
What's poison to a human, to a goat or to a cat,
Could be a tasty morsel to a guinea pig or rat.

Monkeys can eat strychnine, and guinea pigs can too,
Yet just a small amount would cause the death of me and you.
And belladona's something that's as harmless as can be,
If you're a goat or rabbit, yet not for you and me.

Henbane is a poison to a man but not a snail,
Tho' digitalis helps our hearts, it may cause dog's to fail.
Morphine sends a man to sleep, and yet it wakes up cats,
And asprin, safe for humans, causes birth defects in rats.

Thalidomide passed all the tests, on animals galore,
Yet caused bizarre deformities in babies by the score.
A migraine drug called Imetrex, caused heart attack and stroke,
And Zyban caused depression, and killed a lot of folk.

So clearly tests on animals, do nothing but mislead,
They simply hinder progress which is something we don't need.
It's surly time to end these tests along with all the pain,
And forge ahead with real research, enlightened and humane.

Jenny Moxham

Vioxx causes harm sooner than previously thought
While Merck and Co battles thousands of lawsuits over its drug Vioxx, the New England Journal of Medicine has revealed that it does not take 18 months of Vioxx use to increase heart risk. According to the journal, heart risks from using the painkiller could occur after only three months. This revelation will have a significant impact on Merck's 13,000 lawsuits alleging cardiovascular harm from the drug, as it has argued that Vioxx was not to blame for heart attacks and strokes suffered by plaintiffs who used the drug for only a few months. Despite having been 'proven' safe through animal tests, Vioxx was withdrawn from sale in October 2004 after being linked to an increased risk of heart attack and stroke.
Source: The Boston Globe, 27 June 2006.

Australian News

Michael J. Fox Foundation funds Parkinson's disease research
Michael J. Fox, Hollywood actor and Parkinson's disease sufferer, has donated more than $800,000 to an Australian research team to investigate ways to prevent falls and improve the mobility of Parkinson's sufferers. The research will involve a three-year randomized clinical trial to test treatment options, and personal correspondence AAHR has received from research leader Professor Meg Morris has revealed that this research will NOT be involving any animals.
Source: The Australian, 22 June 2006 and personal correspondence.

Drug Companies manipulating trials
A senior cancer specialist has accused large multinational pharmaceutical companies of manipulating some clinical trials claiming that they have deliberately delayed the release of negative findings and are reluctant to fund research into drug toxicity. The claims of Professor Stephen Clarke have been backed up by a number of researchers who believe the public do not always get the full picture about a drug's usefulness and safety
Source: The Age, 7 August 2006.

Green Pages Australia
Green Pages Australia is a database comprising of over 5,000 'green' business listings who have been chosen and recommended for their standout work and contribution to the creation of sustainable communities within Australia. Green Pages has provided AAHR with a free listing. The website 'www.greenpagesaustralia.com.au' launches on 10th October at Federation Square, Melbourne.

News from Overseas

TGN1412 victim may have cancer
One of the volunteers of the tragic TGN1412 UK drug trial is showing early signs of cancer. David Oakley has been told that he has an 'aggressive' form of the illness. His doctors have warned that he may also risk developing multiple sclerosis, arthritis and chronic fatigue.
Source: The Daily Mail, UK, 6 August 2006.

Estrogen in rodent chow can affect scientific studies
Concern has been raised by researchers in the US that routine feed provided to laboratory rats and mice may have skewed the results of research.
The most commonly used chow contains soy which naturally contains phytoestrogens. These chemicals can work their way into the animal's natural estrogen system, altering their physiology and potentially affecting researcher's conclusions on research into cancer, heart disease and studies involving hormones.
Source: Dallas Morning News, 3 August 2006.