BASEL DECLARATION SOCIETY
Report 2012–2013

EDITORIAL

«The Basel Declaration Society – Going Truly International and Promoting Openness»

2013 has been very successful for the Basel Declaration (BD) and its Society, which is now firmly established as the international academic grass-root organization for researchers working with animals and animal welfare scientists. The international nature is exemplified by the recent election of Prof. Ian McGrath (UK and Australia) and Dr. Guiliano Grignaschi (Italy) to the BD board- Welcome and thank you very much!

The BD Society and its members are dedicated to an open dialogue with the general public, lawmakers and other stakeholders on the sensitive issues of research with animals. We are very happy that the number of scientists, research institutions and organizations that endorse the Basel Declaration has risen tremendously in 2013 – currently scientists and research institutions in over 50 countries have undersigned the Basel Declaration and its principles. The BD Society has an established network of voluntary ambassadors in more than 25 countries.

The importance of this ambassador network became evident in the activities that followed the BD Call for Solidarity with the Italian researchers, whose research was destroyed by animal rights extremists. This call resulted in a strong show of international solidarity and active participation of BD ambassadors at public pro-research rallies in different Italian cities. The BD Society office served as an important relay between the scientific community and national organizations such as Pro-Test Italy. This allowed us to rally support for animal research and the correct implementation of the EU directive. This reach-out strategy is a major activity of the BD Society and aims to establish a network of organizations that promote ethically responsible animal research, the 3Rs (refine, reduce, replace) and educate the general public about state-of-the-art research with animals.

A second major event in 2013 was the BD Conference in London on "Transparency in Animal Research: Implementing Openness in Publication and Communication". Stakeholders representing all relevant fields and organizations got together for two days of presentations and intense discussions with participants from around the world. The two main topics concerned the improvement of publication standards and open access to the primary results of studies involving animals. The resulting BD position papers (see the BD website) provide a clear roadmap of how to deal with these issues. The timeliness of the London Conference is best illustrated by the current debate on the reproducibility of the results of biomedical research in the international press and scientific journals.

All these activities would not have been possible without generous sponsorship. As these and other issues concerning animal research will keep us busy for the years to come, we hope that you will continue to support the Basel Declaration as society member, donor and/or sponsor – your support and engagement will help us to make the difference!

Thank you so much for your generous support of the Basel Declaration ideals and activities!

Prof. Dr. Rolf Zeller
President of the Basel Declaration Society

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ACTIVITIES AT A GLANCE

- 19 November 2012
  General Assembly
- 29 January 2013
  Presentation of the BDS at the EPFIA in Brussels
- April / May / June 2013
  Call for Solidarity
  Some 6000 signatures collected in one month
- 1 June 2013
  Call and participation in a demonstration in Milan
- 10 – 13 June 2013
  Booth at the FELASA Congress in Barcelona

- 12 June 2013
  Meeting of national animal research defence organisations in Europe Strategic communication and advocacy on animal research together with Understanding Animal Reserch (UK) and Gircor (France)

- 1-2 July 2013
  Transparency in Animal Research – Implementing Openness in Publication and Communication together with Understanding Animal Research (UK)
- August 2013
  Basel Declaration Award for Education in Animal Research. The young Italian researcher Dr Chiara Ruzza from the University of Ferrara, Department of Medical Sciences, won the second Basel Declaration Award for Education in Animal Research. She attended a five-day intensive Introductory Course in Laboratory Animal Science at the University of Zurich, Switzerland, in August 2013 to gain technical knowledge and practical skills for the responsible and careful handling of laboratory animals before, during and after an animal experiment. She committed to apply this knowledge in her own day-to-day laboratory work, and to pass it on to fellow researchers in Italy.
- 19 September 2013
  Call and participation in a rally in Rome, Italy

Giuliano Grignaschi speaks at the rally in Rome

- 7 October 2013
  Call for support of a petition to Italian and EU politicians (more than 12,000 signatures)
- 30 October 2013
  GOEvol III Symposium on Evolutionary Biology
  Georg August Universität Göttingen
  Talk on animal experimentation issues entitled "Basic biomedical animal research – the why, how, when and if" in the context of a workshop on "Bioethics of animal testing & genetically modified organisms".
- 2 November 2013
  Participation in a podium discussion at the "festival della scienza" in Genoa
- 8 November 2013
  Call for support of a petition to Belgian and EU politicians (more than 1300 signatures)

TRANSPARENCY IN ANIMAL RESEARCH – IMPLEMENTING OPENNESS IN PUBLICATION AND COMMUNICATION

At the conference held in London on 1–2 July 2013, we welcomed more than 100 participants. Four task forces, including researchers but also representatives from the publishing industry, from various associations, and from animal rights groups intensely debated to come to a common position.

Workshop summaries

1. Improving publication standards of research involving animals:

Despite some successful initiatives aimed at improving publication standards, a significant proportion of publications still lack sufficient information regarding the planning, execution and/or statistical analysis of research projects. This workshop produced the following suggestions for improvement; acknowledging that implementation of these best practice publication standards will require cooperation from all stakeholders.

- A common set of guidelines (concerning the reporting, design, execution and analysis of research projects) implemented across all journals.
- Journals should encourage the publication of all details relevant to the research, analysis, and methodology; and should require a description of efforts taken to comply with the 3Rs (thereby making this information available for scrutiny).
- Scientists and editors should cultivate a culture of rigorous critical assessment and review of animal studies.
- Null results (those not affirming the hypothesis) should be published to avoid unjustified duplication, publication bias and erroneous 'first in man' studies.
- All robust primary data should be made available in open-access, curated databases.
- Students and researchers should be trained in best experimental practice and ethics of animal research, consistent with publication guidelines, in order to facilitate high standards of reporting.

Ian McGrath, Editor in Chief of the British Journal of Pharmacology

2. Open Access to maximise the value of animal research:

The scientific research community, including both the public and private sector, is committed to maximising the value of data generated from animal research in order to enhance the design and quality of future studies. This can be achieved through increased sharing of, and access to, experimental design, methodologies, and non-competitive data.

Methods to improve access to this information were considered under the following headings:

Publication of results: There should be standardised and approved guidelines for the publication of research involving animals, with opportunities and incentives to publish well-designed studies which produce null results. It should be made clear how to access data and materials related to the paper; and raw data related to the publication should be held in a recognised database.

Funding bodies should require details of publication plans to be outlined in grant proposals; and it should be a requirement for all grants for research using animals to publish something of journal quality.

Accessibility of resources: Further use of repository and resource frameworks for sharing animal models, protocols, genetic information, and cross-referenced data should be encouraged; and their sustainability secured by increased EU, other public sector, and charitable funding. Researchers should be encouraged to use services such as INFRAFRONTIER or the IMPC, which use high-end technology and common standards and protocols to minimize impact on animals and maximise scientific output. Repositories (e.g. INFRAFRONTIER/EMMA) can connect researchers working on specific disease models or drug targets with others who have used similar animal models.

Accessibility of data: Mechanisms to increase sharing though cross-linked, open-access repositories and databases should be developed; as well as a central portal through which the data from all animal studies can be reviewed. There should be improved awareness and training in effective systematic reviews and meta-analyses as part of the study design process (in this way, the value of existing data can be realised, before further research is undertaken). To maximise the benefit of data, it is important to present it in a format that is conducive to scrutiny and interrogation.

Rolf Zeller (BDS) and Wendy Jarret (UAR)

In the pursuit of open access to information, consideration must nevertheless be taken of that which is commercially sensitive and protected by property rights.

3. Implementing the 3R principles in daily research practice- the next steps 2013

It is important to develop novel methods and approaches to increase the impact of the 3Rs; to promote the implementation of the 3Rs into the planning of research projects; and to provide researchers with appropriate incentives for implementing the 3Rs into their day-to-day research routine.

The following methods were proposed to improve the implementation of the 3Rs:

- It is important to achieve a unified approach in the dissemination of the 3R philosophy within the research community and general public (this could be supported by incentives e.g. awards) and there should be a greater emphasis on the 3Rs in higher educational curriculums.
- The 3Rs should be frequently reassessed and updated; similarly, novel methods to assess the validity and success of 3R research projects should be developed by both granting agencies and publishers.
- Senior management should cultivate a culture of responsibility and accountability in which all staff share a common commitment to: challenging the necessity for the use of animals through rigorous ethical review; maximising the use of alternative methods; reducing the number of animals used through efficient experimental design, and reducing suffering through refinement of experimental practice, animal husbandry, and care.
- Throughout Europe, increased funding should be provided for research projects that seek to advance the implementation of the 3Rs.

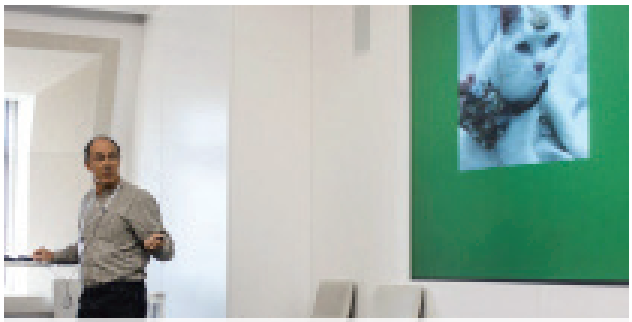
4. Use of Higher Mammals in Research

Mammals have historically played an important role in research and medical breakthroughs, and they will continue to do so. They are required to study complex biological processes and model conditions relevant to both humans and other mammals.

Rolf Zeller, President of the Basel Declaration Society

Due to their highly evolved nervous systems, and the increased level of public concern, the use of higher mammals (such as: cats, dogs, pigs and non-human primates) in research requires scientists to embrace a corresponding increased level of accountability and transparency in the communication of their research. It also necessitates a stringent harm/benefit analysis at the beginning of each research project and careful selection of the most appropriate animal model. An appropriate animal model will, in turn, contribute to the fulfilment of the 3Rs by improving the statistical reliability of the analysis and achieving the best possible correlation with the study aims.

All those involved in the research with animals (namely: research teams, veterinarians, caretakers, and administrative authorities) must continue to improve animal welfare based on novel scientific findings; staff must be adequately trained in experimental techniques and the specific welfare needs of the animal entrusted to them. Some higher mammals may have needs which are difficult to accommodate in a laboratory setting, and this should be considered in the planning and evaluating of such studies.



Kevan Martin, University of Zurich, Switzerland

CALL FOR SOLIDARITY

All signatures ready for the handover

On 25 April, we received news from Prof. Francesco Clementi, University of Milan, that on Saturday April 20, Italian animal rights extremists invaded laboratories at the University of Milan and the associated National Institute of Neurosciences to destroy a large number of important research projects. As of 30 April, we have formulated the Call for Solidarity, prepared the website and in May, we gathered almost 6000 signatures from researchers around the world (see: http://www.basler-deklaration.ch/projects/call-for-solidarity/), who condemned these attacks.

The research destroyed by the attacks focuses on currently incurable diseases, such as autism, Parkinson's, Alzheimer's, multiple sclerosis and many other still untreatable diseases. Members of the "Fermare Green Hill" group abducted about 100 purpose-bred animals that require special care. Therefore, it is unlikely that they can survive their "liberation". In addition, the extremists maximised damage by removing all cage signs used to identify the animals. This renders all mice in experiments useless and defies the supposed "animal liberation".

According to Prof. Clementi, a signer of the Basel Declaration and internationally-renowned pharmacologist, the financial damage likely exceeds several 100'000 Euros, with the scientific damage being even far greater. Years of research have been senselessly destroyed.

Text of the Call for Solidarity

On April 20, 2013 a group of animal rights extremists invaded laboratories at the University of Milan, illegally removed about 100 animals and destroyed numerous highly valuable research projects. The attack was covered in national and international media1.

We, the signatories, call for solidarity and support for the affected researchers and

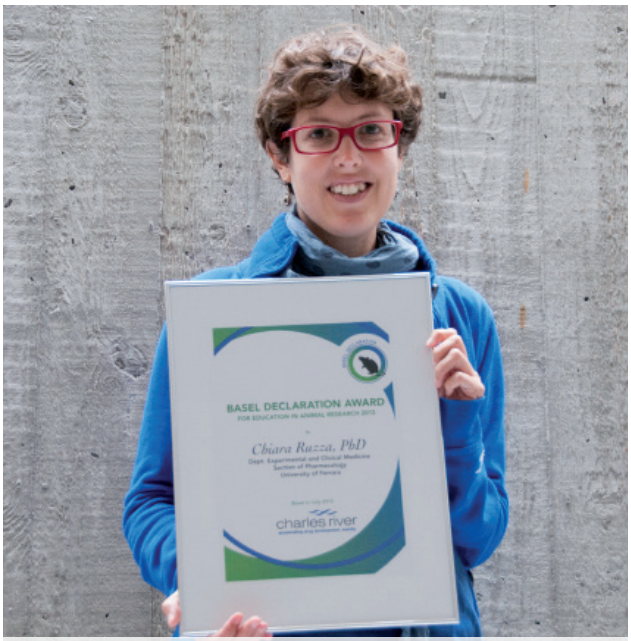
- ask society to trust in our scientists and raise any concerns on what we do – and how we do, what we do – in an open, transparent dialogue, based on mutual candor and respect
- call upon media to provide fair, balanced and fact-based coverage on biomedical research issues, acknowledging that science is intrinsically complex, yet an essential basis for all knowledge-based economies
- ask moderate animal welfare organizations to refrain from any acts of extremism while using legitimate platforms and individual dialogue to raise their legitimate concerns
- call upon police, law enforcement agencies and policy makers to apply a "zero-tolerance" strategy towards any act of animal rights extremism
- ask everyone who is concerned about progress in the area of neuroscience to submit proposals at www.basel-declaration.org on how the financial damage of our Milan colleagues can be alleviated

Giuliano Grignaschi hands over the signatures of the call for solidarity Bice Chini

THE BASEL DECLARATION AWARD FOR EDUCATION IN ANIMAL RESEARCH – THE REPORT OF DR CHIARA RUZZA

As the winner of the 2013 "Basel Declaration Award for Education in Animal Research", I had the opportunity to attend the 'Introductory Course in Laboratory Animal Science' (Zurich, August 2013), organised by the Institute of Laboratory Animal Sciences of the University of Zurich. This was a 40 hour course of both lectures and practical training (with mice and rats), certified by the Federation for Laboratory Animal Science Associations (FELASA, category B).

The course was very well organised; providing an exhaustive overview of situations and problems encountered by individuals working with laboratory animals. The course had a number of objectives, among them were: animal welfare regulation and ethical principles, standardization in husbandry, nutrition, transportation and handling, managing transgenic mice colonies, health monitoring and pain assessment, principles of surgery and anaesthesia, and guidelines for euthanasia. The practical training provided focus on experimental design and execution, the correct handling of mice and rats, the application of substance, and the collection of samples. A high volume of interesting and useful material was provided throughout the course (namely: papers, videos and presentations); and those teaching the course were well prepared and delivered a high standard of teaching.



Chiara Ruzza

It is now mandatory for me to organise a similar course at my own University (University of Ferrara, Italy). Notably, this kind of education is not compulsory in Italy; but it is now necessary to upgrade the standard of our animal research. The need for adequate training and education for those conducting animal research is not only a principle of the Basel Declaration, and a recommendation of FELASA, but it is also a requirement of the European Directive 2010/63/EU for the protection of animals used for scientific purposes.

The course will be addressed primarily to PhD students of the Life Sciences, but the invitation to attend will be extended to all researchers who are working with animals at the University, in addition to, (perhaps) our animal technicians. Hopefully, in the future, we can extend the scope of the course to include other Italian Universities.

The first course, which I plan to organise in the first semester of next year, will be a short one (of 8 hours). I have already written a letter of proposal to the heads of the PhD programs, and to the professors in charge of our animal facility; they have received this proposal positively.

Dr Chiara Ruzza, University of Ferrara

PUBLICATIONS

Mice Times, a magazine showcasing true success stories in basic research in which animals play a central role, is published 2-3 times a year in English (Mice Times), German (Mausblicke) and French (lécho des souris). In 2013 the following editions were issued:

08 September 2013:
From cerebral pacemaker to cell replacement therapy

07 February 2013:
3R is routine today

To see all available editions please visit:
www.basel-declaration.org/publications

08 | August 2013

MICE TIMES

From cerebral pacemaker to cell replacement therapy
Primate studies open up new avenues in the treatment of Parkinson's disease

Hans-Peter Ludin, 77, formerly Head of Neurology at St. Gallen Cantonal Hospital, witnessed them all during his medical career: the little steps forward and the major advances that have been made in the treatment of Parkinson's disease over the last 50 years. In the 1950s and 1960s there were the initially rather clumsy attempts of doctors to overcome the disease using stereotactic surgery. Here, tissue in certain areas of the brain was coagulated (destroyed) with electric currents or with heat or cold, so that the contralateral tremor could be suppressed. The start of the 1970s then saw a major breakthrough when the launch of the dopamine replacement substance L-dopa laid the foundations for effective pharmacological treatment of Parkinson's. In the 1980s and 1990s came the gradual establishment of deep-brain stimulation, i.e. the stimulation of targeted areas of the brain, which is a standard therapy today especially for patients with advanced disease. The fight against Parkinson's, then, has seen significant advances over the decades. This success has particular importance for a society whose population is steadily aging, as Prof. Ludin points out: "Parkinson's will increase further because people are getting older. Society faces a huge challenge here, especially since we know that people with Parkinson's have a five times higher risk of developing dementia."

Treatment success right on target

In present clinical practice, Parkinson's is treated mainly with drugs in the first few years. If the disease is advanced, then deep-brain stimulation is used; experts estimate that this is the case in around 15 to 20 percent of patients. Dr. Thomas Funk is principal consultant at the Klinikum Frankfurt/Oder GmbH and one of the pioneers of this treatment method. The cerebral pacemakers used by Funk consist of a four-pole electrode with a diameter of 1 mm.

Fig. 1 Introduction of the electrode

The electrode is surgically placed in the subthalamic nucleus. Here, with a voltage of around 2 V and a frequency of 180 Hz, it stimulates a group of cells that no longer work properly and thus give rise to the tremor seen in Parkinson's patients. The electrical stimulation regulates the overactive cells, bringing them down to a normal level of activity and thus restoring the 'healthy' balance between the build-up and release of tension. The electrode receives electrical impulses from a pacemaker that is usually implanted in the pectoral muscle or abdominal fat. The cerebral pacemaker produces an improvement

Fig. 2 Inter-operative control of the electrode with image converter, conductor, transducer

Fig. 3 Inter-operative test of the effect and side-effect

in more than 90 percent of patients. "The procedure gives patients an extra ten years. We return them to the condition characterized by the disease ten years ago", says Funk. Full therapeutic success with a minimum of side effects is only achieved, however, if the

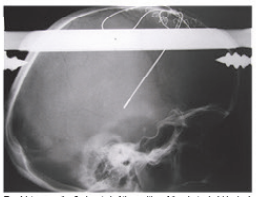


Fig. 4 Inter-operative final control of the position of the electrode (side view)

surgeon places the electrode with millimeter accuracy. Otherwise, there is a risk of speech or movement disorders. A lot of research was needed in the last few decades to determine the suitable sites for the electrode. This included individual therapeutic studies in patients. "Most problems can be clarified in studies with rodents (rats and mice). But in such complicated disorders as Parkinson's there are certain questions that can only be answered with studies in monkeys", says Prof. Andreas Kupsch, neurologist at the University Clinic of Magdeburg, who played a defining role in helping to develop the treatment method from 1990 to 2010.

Kupsch refers to studies in the early 1990s with which the behavior of the subthalamic nucleus was investigated and which made possible the triumph of the cerebral pacemaker in the years that followed. He believes primate studies are also indispensable in Parkinson's research: "The similarity of the network circuits in the brain is much closer between monkey and human that it is between rodent and human. In some cases, therefore, it is necessary to fall back on non-human primates, i.e. monkeys, for research studies. Anyone who wants to investigate how dystonia (a movement disorder) occurs in the hand cannot do this in the paw of a rat. You need monkeys for this, because the function of the hand is more similar between monkey and human", says Kupsch. Meanwhile, the success of deep-brain stimulation extends far beyond Parkinson's. The method is being used in more and more diseases, such as dystonia and also depression, obsessive-compulsive disorder and alcohol addiction. Work is also under way on Alzheimer's.

Connective tissue cell becomes nerve cell

For some years, scientists have now opened up a new chapter in Parkinson's research. The magic phrase is cell replacement therapy. Once again, researchers are stepping out into uncharted territory with a new form of treatment. Once again it involves complex procedures in the human brain that are inevitably accompanied by risks. Before cell replacement therapy becomes available for patients, extensive studies in the animal model are called for. "I would consider experiments in humans very critical and unethical at the present time, because we don't yet know whether the treatment really offers a great opportunity for relief or even a cure", says Prof. Rüdiger Behr, stem cell biologist at the German Primate Center (DPZ) in Göttingen. Parkinson's is not a disease that runs an acute, life-threatening course, so higher ethical hurdles apply before a new therapy can be tested in humans than is the case with fatal diseases, says Behr.

Many researchers around the world are working on the development of cell replacement therapy. The basic idea is simple in principle: The aim is to cure the brain tissue that is damaged in Parkinson's patients – the dopamine-producing nerve cells in the substantia nigra of the midbrain – by transplanting healthy replacement cells. Feverish research is under way today in an attempt to cultivate suitable replacement cells. The basis for this research is a method that enables such replacement cells to be

MEDIA ECHO

- Sonntagszeitung, 13. Oktober 2013: Schlampereien im Tierlabor. Die Basel Declaration Society setzt sich dafür ein, dass Fachzeitschriften weltweit rigorosere Publikationsstandards durchsetzen und eine Datenbank erstellt wird, auf der alle Resultate aus Tierversuchen, auch negative, abgespeichert werden.
- Biomed, 18.September 2013: Improving ethical animal research: Rolf Zeller on the aims of the Basel Declaration Society
- BZ Basellandschaftliche Zeitung, 15. September 2013: Tierversuche werden zunehmend auch von Tierschützern gebilligt
- DPZ Deutsches Primatenzentrum, 04. September 2013: Tierversuche: Neues Positionspapier Wissenschaftler und Tierschützer verabschieden mit DPZ-Beteiligung ein gemeinsames Positionspapier auf der Tagung «Transparency in Animal Research».
- Interpharma, 28. August 2013, Junge Forscherin gewinnt «Basel Declaration Award» Zum zweiten Mal vergibt die Basel Declaration ihren «Award for Education in Animal Research». Preisträgerin Chiara Ruzza, PhD in Pharmakologie, besucht während einer Woche einen Kurs für Tierexperimentelle Forschung nach den Regeln der 3R.
- Interpharma, 8. Juli 2013, Forschung mit Tieren: Transparenz fördern und fordern | Vertrauen, Transparenz und Kommunikation bei Tierversuchen fördern. Mit der Basel Deklaration bekennen sich mittlerweile über 2400 WissenschalterInnen zu diesem Ziel. Eine Tagung in London zeigt das internationale Interesse an diesem Thema.
- BioMed Central blog July 4, 2013 The past two days have seen scientists, animal welfare officers, funding agencies and journal editors gather together in London for the 3rd Basel Declaration Society Conference. The focus? To discuss ways in which these various groups can collaborate to promote openness and transparency in animal research.
- Spiegel-online, 28.6.2013 Initiative «Pro-Test»: Warum Italiener für Tierversuche demonstrieren. Wenn sich Forscher im Rahmen der Basler Deklaration oder in Form von «Pro-Test Italia» für Tierversuche aussprechen, wollen sie unterm Strich so wenig Tierversuche wie möglich. Sie wollen aber, dass Experimente stattfinden können, ohne dass Labore verwüstet und Wissenschaftler bedroht werden.
- Nature, 03 June 2013, Italian scientists fight back on animal testing: “These guys realized that the public doesn’t know what research is, and what we do in our laboratories,” said Giuliano Grignaschi, a spokesperson for the Basel Declaration Society
- Nature, 08 May 2013, Voice of Pro-Test / Confidence is rising among scientists defending animal research. It should be encouraged.
- Nature, Seven days: 3–9 May 2013, Science solidarity

Members

Individual Members: 150 (per 31.12.2012: 68)
Institutional Members: 2 (per 31.12.2012: 1)

Signers of the Basel Declaration

Individual Signers: 1907
Institutional Signers: 29

Ambassadors 139

Twitter

In April 2013, we began a Twitter account under the username @BaselDec. As of November 2013, some 247 Tweets have been made and 145 people are following the site.

Pay Pal

Since the summer of 2013, Pay-Pal has been installed on the Basel Declaration Society Website. This significantly simplifies the process of paying dues by our members from around the world. We hope donations will also be made through this channel.

Become a member of the Basel Declaration Society

We look for your support to publicly show that we are committed to the 3R principle (Replace, Reduce, Refine), i.e., plan and carry out animal testing in your area of expertise with utmost care, and contribute to providing society with open and transparent information about animal experiments.

We encourage scientists, veterinarys, animal caretakers and everyone with an interest in supporting the Basel Declaration principles for animal research to become a member of our society:

Membership fee for individuals: CHF/€/$ 50 per year.

The suggested membership fees for institutions / organisations are CHF/€/$ 500 per year, but the exact membership fee for institutions and organizations should be discussed with our management office during the process of joining the BDS.

Please complete the membership form on:
www.basel-declaration.org and pay your
membership fee by paypal (klick the bottom on
www.basel-declaration.org)

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