Implementing the IAVE consensus author guidelines on animal ethics and welfare for veterinary journals

Celia M Marr
EVJ publishes and promotes high quality peer-reviewed research that expands the knowledge base about equids, informs veterinary science and improves clinical practice.
Equine Veterinary Journal

- Owned by British Equine Veterinary Association
- Currently published in partnership with Wiley
- Most successful single-species veterinary journal
  - Impact Factor 2.286, 8/143 in Veterinary Sciences
- Submissions sourced internationally with bias towards UK and US
- Descriptive clinical reports are cited as often as research articles
The least downloaded articles are

- In vitro studies
- Studies with the aim of anatomical/physiological knowledge
- Basic research studies
- The following disciplines:
  Reproduction, biomechanics, cell and molecular biology, respiratory, behaviour and husbandry
Equine Veterinary Journal: Editors and Editorial Boards

• Editor-in-chief, Celia Marr, UK, (200), IEA, internal medicine, miscellaneous, editorial
• Deputy editor, Tom Stout, The Netherlands, (25), reproduction, IEA, EIC competing interests (UK private clinics, current and former collaborators)
• North American and Reviews Editor, Deb Sellon, US
• Statistical Editor, Rob Christley, UK
• Associate editors
  – Peter Clegg, UK, (50), musculoskeletal biology and orthopaedics, IEA
  – Rene Van Weeren, The Netherlands (50) musculoskeletal biology and orthopaedics
  – Duncan Maskell, UK (25) microbiology
  – Tony Pease, US, (25) diagnostic imaging
  – Louise Southwood (50) surgery, miscellaneous
• Editorial Consultant Board - 36 individuals (4 Senior, 28 Discipline-based, 2 Clinical) committed to providing 6 reviews per year, advise on general editorial policy, IEA
• Study Design and Data Analysis Board - 36 individuals committed to providing 6 statistical reviews per year, advise on SD&DA policy
Ethical Animal Research

• Subjects
  – equids reared for in vivo experimental studies
  – equids donated for in vivo or in vitro studies
  – client owned horses
  – tissues obtained from abattoirs
  – archived material obtained from diagnostic services (tissues, fluids, images)
  – in silico using public databases (Racing and Sporting Authorities)

• Compliance with international guidelines
  – IAVE consensus author guidelines adopted January 2012
  – ARRIVE guidelines adopted January 2014
    • documented within a section of our Author guidelines encouraging the use of various analytical and reporting guidelines, not our "Ethics" section
2.2. Use of animals in research

When experimental animals are used, the methods section must clearly indicate that adequate measures were taken to address the welfare of the horse involved. Experiments should be carried out in accordance with permission of, and adequate monitoring by, a recognised ethical committee of the institute or university of origin and be within the legal framework of the country in which the work was performed. All studies using equine subjects should include an explicit statement in the Materials and Methods section identifying the review and ethics committee approval for each study, if applicable. Editors reserve the right to reject papers if there is doubt as to whether appropriate procedures have been used and also to insist that information is provided in the text as to the measures taken to protect the welfare of subjects and the outcome of procedure undertaken in respect to any pain or suffering caused.

- Implicitly describing experimental not clinical research
- Lacks any requirement for owner informed consent
- Does not encompass studies from non-University, non-institutional sources i.e. private veterinary practices
IAVE consensus author guidelines 2010

Key Principles Used in Developing the Author Guidelines

1) All journals publishing studies in which experimental or client owned animals are used should have a clear editorial policy on animal welfare ethics.
2) The policy should appear prominently in the instructions for authors and referees.
3) Guidelines should indicate that recommendations apply to all vertebrate (and specified invertebrate) animals and not just those reared for and used in the laboratory.
4) Policies should indicate any journal-specific requirements for animal welfare and demand adherence to relevant institutional, national, and international guidelines.
5) Policies should make clear that failure to meet ethical concerns regarding animal welfare will result in manuscript rejection.
6) Journals should require author declaration of compliance with animal welfare and ethical guidelines.
IAVE consensus author guidelines 2010

Animal ethics-based criteria for manuscript consideration
1) Follows international, national, and/or institutional guidelines for humane animal treatment and complies with relevant legislation;
2) Has been approved by the ethics review committee at the institution or practice at which the studies were conducted where such a committee exists;
3) For studies using client-owned animals, demonstrates a high standard (best practice) of veterinary care and involves informed client consent;
4) Meets all additional ethical standards set by [journal name], as follows: [describe any journal-specific animal ethics and welfare guidelines here].
EVJ Author Guidelines: 2012

Manuscripts will be considered for publication only if the work detailed therein:

- Follows international, national, and/or institutional guidelines for humane animal treatment and complies with relevant legislation in the country in which the study was conducted;
- For studies using client-owned animals, demonstrates a high standard (best practice) of veterinary care and involves informed client consent;
- Has been approved by the ethics review committee at the institution, hospital or practice at which the studies were conducted where such a committee exists;
- **Where such a committee does not exist, authors are expected to have conducted their research in a manner likely to be approved by ethics committees in most countries.**
Ethics Committees

• Institutional committees appear to be overseeing experimental research in all countries EVJ has received manuscripts from (53 countries, 2011-13)

• Rarely mentioned in manuscripts originating from private practice (UK, US/Canada, Brazil, European mainland)

• EVJ's current approach is to aim to ensure that accepted studies achieve appropriate ethical standards rather than insist on process

• Approval by an institutional ethics committee does not guarantee EVJ will not reject on ethical grounds

• Some UK ethics committees provide "retrospective" approval

• Animal medicines regulations vary considerably from country to country with respect to need for approval of novel drugs for clinical practice
Ethical review for practice-based research: a report by a joint RVCS/BVA working party, 2013

VSA = veterinary surgeons' act, defines what vets can do and what non-vets cannot do

ASPA = Animals Scientific Procedures Act 1986 aka "Home Office Approval"

Animal Test Certificate = issued by the Veterinary Medicines Directorate to allow clinical trials
Accessing Ethical Review

1. Collaboration with colleagues in research institutes that already have ethical review committees

2. Purchase of ethical review services from institutions that have ethical review committees

3. The establishment, under the auspices of the RCVS, of a national independent body available to practitioners for ethical review of veterinary practice based research

4. Setting up ad hoc ethical review process (the "DIY" option).
• www.rcvs.org.uk/ethicalreviewreport

• Veterinary Record 2013, 172, 222-223, doi: 10.1136/vr.f1252
EDITORIAL

Ethical, scientific and practical standards in clinical practice research

J. Bertone

First published: 6 June 2013  Full publication history
DOI: 10.1111/evj.12062  Citing literature

Equine welfare and veterinary medicine need field research by competent veterinarians. Animal welfare considerations need to meet the highest standards to promote the value of field research results and to allow us to meet the public and professional expectations of animal welfare and patient care. In common with other veterinary journals, EVJ insists that authors assure that ethical and legal requirements have been met at the time of manuscript submission [1], and practitioners planning to undertake a research study should ensure that they are aware of the details of such requirements. These are recommendations and guidelines that make sense.
IAVE consensus author guidelines

Prior to acceptance of a manuscript, to verify compliance with the above policies, the authors must: [journals may opt for one or more of the following]

1) Sign a letter certifying that legal and ethical requirements have been met with regards to the humane treatment of animals described in the study;

2) Specify in Materials and Methods the ethical review committee approval process and the international, national, and/or institutional guidelines followed.
Implementation

Obtaining and assessing ethical information?

• up to 2012 - relied on authors to insert information into Material and Methods and reviewers to check it
• 2013 - added specific Legal and Ethical section to submission form and transferred responsibility to SEs to check it
  – EVJ has double blind review
  – SEs carry more responsibility than reviewers
  – SEs are more knowledgeable about EVJ policy than reviewers
Submissions must be accompanied by a statement, **in our submission form**, certifying that legal and ethical requirements have been met with regards to the humane treatment of animals described in the study and specifying the ethical review committee that has overseen this process and/or the international, national and/or institutional guidelines followed. **This information will be included in the Declarations Section.**
Elements of valid informed consent

• Disclosure
  – researcher must provide sufficient information, in lay language, for the owner to understand the study question and methods, potential benefits to their animal and any risks

• Capacity
  – appropriate age group
  – difficult for researchers to judge or monitor owner understanding

• Voluntariness
  – no penalties if decline, patients receive the same level of care as those in the study, owner aware of alternatives
Why have informed consent?

• Empower the owner to make decisions regarding their animal's care
• Allow the owner to express individual rights regarding veterinary management of their animal, the specific research, and research in general
• Maintain rights to privacy
• Protect individual from wasting their time on poor quality research
• Consent for investigation and treatment is not consent for research
• Does it always have to be written?
"studies using client-owned animals………
and involves informed client consent"

<table>
<thead>
<tr>
<th>July issue 5/19</th>
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<tbody>
<tr>
<td>Colic in competing endurance horses presenting to referral centers: 36 cases</td>
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<td>Complications after Two Transphyseal Bridging Techniques for Treatment of Angular Limb Deformities of the Distal Radius in 568 Thoroughbred Yearlings</td>
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<td>Postoperative infection, pyrexia, and perioperative antimicrobial drug use in surgical colic patients</td>
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<td>Characteristics of Thoroughbred and Quarter Horse racehorses that sustained a complete scapular fracture</td>
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<td>Possible role of carpal hyperextension in superficial digital flexor tendinopathy</td>
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<td>Complex dynamic upper airway collapse: Associations between abnormalities in 99 harness racehorses with one or more dynamic disorders.</td>
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<tr>
<td>Treatment of subchondral cystic lesions of the medial femoral condyle of mature horses with growth factor enhanced chondrocyte grafts: A retrospective study of 49 cases.</td>
</tr>
<tr>
<td>Relative prevalence of upper respiratory tract obstructive disorders in 2 breeds of harness racehorses (185 cases: 1998-2006)</td>
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January 2013: submission form

"Please certify that legal and ethical requirements have been met with regards to the humane treatment of animals described in the study and specify the ethical review committee that has overseen this process and/or the international, national and/or institutional guidelines followed. **All prospective clinical studies** must have owners informed consent and this must be explicitly confirmed here and stated in your methods section."

Typical response was "I certify that legal and ethical requirements have been met with regards to the humane treatment of animals described in the study"

Part 2 - details of processes and part 3 - owners informed consent were not being addressed
IAVE consensus author guidelines 2010

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6) Journals should require author declaration of compliance with animal welfare and ethical guidelines.
May 2013 submission form

"Give specific details of the ethical review and approval from local or national bodies that relate to the study. For prospective clinical research and questionnaire-based studies using client-owned animals, owner informed consent must be stated here."

Typical response from clinical researchers:
"The University of Newmarket Ethical Review Committee approved the study protocols."
or "Not applicable"!

Part 2 - i.e. owner informed consent still not being addressed
1. Give specific details of the ethical review and approval from local or national bodies that relate to the study.

2. For all studies involving client owned animals or material derived from client owned animals (images, tissues etc), please state whether you had explicit informed consent for the study (yes/no/NA).

3. If you have answered "no", does the hospital(s) and/or laboratories from which materials were derived for this study consistently use admission/consent form that includes an option for owners to opt out of research studies? (yes/no/NA).
Key modifications in 2014

• No longer limit owner informed consent requirement to "clinical research and questionnaire-based studies using client-owned animals"

• Added a question designed to accommodate retrospective research, studies on archived samples etc collected using a general "treatment and investigation consent form" provided that form gives client the opportunity to opt out.
Better information means better care

What are the benefits of sharing my information?

Sharing information about the care you have received helps us understand the health needs of everyone and the quality of the treatment and care provided.

It also helps researchers by supporting studies that identify patterns in diseases, responses to different treatments, and the effectiveness of different services.

Your choice will not affect the care you receive.

This leaflet contains important information about your health records.

You, and everyone who lives with you, should read this leaflet carefully. It is important that everyone knows how we share, protect and use information about their health.

You have a choice.
Information will also help us to:

• find more effective ways of preventing, treating and managing illnesses
• make sure that any changes or improvements to services reflect the needs of local patients
• understand who is most at risk of particular diseases and conditions, so those who plan care can provide preventative services
• improve your understanding of the outcomes of care, giving you greater confidence in health and social care services
• guide decisions about how to manage NHS resources so that they can best support the treatment and care of all patients
• identify who could be at risk of a condition or would benefit from a particular treatment
• make sure that NHS organisations receive the correct payments for the services they provide.

What will we do with the information?

We will only use the minimum information needed to improve patient care and services.

We are very careful with the information and we follow strict rules about how it is stored and used, and have a thorough process that must be followed before any information can be shared.

When we share information we will make sure we do so in line with the law, national guidance and best practice. Information that we publish will never identify a particular person.

What choice do I have?

We have explained how useful information about you is, and the steps that we take to protect your privacy. However, you may want to prevent confidential information about you from being shared or used for any purpose other than providing your care (except in special circumstances allowed by law, such as when there is a public-health emergency).

Do I need to do anything?

If you are happy for your information to be shared you do not need to do anything. There is no form to fill in and nothing to sign. And you can change your mind at any time.

If you have any questions or are not happy for information about you to be shared, speak to your GP practice.

If you do not want information that identifies you to be shared outside your GP practice, please ask the practice to make a note of this in your medical record. This note will prevent your confidential information from being used other than in special circumstances.

Information from other places where you receive care, such as hospitals and community services, is collected nationally. You should also let your GP practice know if you want to prevent the information from those places being shared.

The practice will make a separate note of this in your medical record.

You may have already asked for information about you not to be shared with others, such as your medical record being shared for your care. You still need to let your GP practice know if you have concerns about your information being shared for the purposes described in this leaflet.

Where can I get more information?

Visit the NHS Choices website at: www.nhs.uk/caredata

for more information, a list of common questions, or another format of this leaflet.

Speak to staff at your GP practice.

Call our dedicated patient information line on: 0300 456 3531

This line also offers translation and text phone services.

More details about how we look after confidential information and how it may be used can be found on the website at: www.hscic.gov.uk/patientconf
Response to Guardian story “NHS patient data to be made available for sale”

NHS England's Chief Data Officer Dr Geraint Lewis said: “NHS England and the Health and Social Care Information Centre (HSCIC) welcome the increase in public awareness and debate about NHS data usage following the nationwide distribution of the leaflet ‘Better Information Means Better Care’.

“It is vital, however, that this debate is based on facts, and that the complexities of how we handle different types of data are properly understood. Patients and their carers should know that no data will be made available for the purposes of selling or administering any kind of insurance and that the NHS and the HSCIC never profit from providing data to outside organisations.”

NHS medical records database halted amid concerns

After days of crisis talks officials agree to shelve the programme for six months and to launch a publicity campaign explaining the scheme and ensuring individuals are aware of their right to opt out
7.3.2.iii Retrospective studies may also require ethical approval despite the fact that no prospective clinical interventions are planned. This is because patient and owner data will be collected; investigators must have ethical review for their data collection methods and appropriate data protection methods. Review may be required if stored data are to be used retrospectively for purposes other than those for which they were collected.

- Ethical committee oversight not currently required by this journal: retrospective study of clinical records. Explicit owner informed consent for participation in this study was not stated.
- Ethical committee oversight not currently required by this journal: procedures were performed as part of clinical investigations. Explicit owner informed consent for participation in this study was not stated.
7.3.1 Questionnaires to be sent to owners retrospectively must also have ethical approval (see non-interventional research).

7.3.4i. Where humans are providing information or participating then the ethical review process should involve appropriate medical and/or social science research expertise.

7.4.3. There are also likely to be ethical issues involved with most if not all questionnaires and advice should be sought. Note that this is always required in NHS or medical research related to patients, students or human subjects. Matters for consideration include anonymity, self-incrimination, data protection and unanticipated distress or psychological harm.

- EVJ require copies of questionnaires for peer review and online publication
- Not specifically mentioned in current ethical section of submission form
- Not specifically listed in SE check list
Organ scandal background

The scandal at Alder Hey Children's hospital centres on the retention of hearts and organs from hundreds of children.

The organs were stripped without permission from babies who died at the hospital between 1988-1996.

Hospital staff also kept and stored 400 foetuses collected from hospital around the north west of England.

The findings of an inquiry into the affair have been described by Health Secretary Alan Milburn as "grotesque" and helplines have been set up to deal with calls from distressed parents.

A pathologist may face criminal charges after a damning report into the "illegal stripping" of thousands of body parts from dead babies.

An official inquiry found that Professor Dick van Velzen was allowed to systematically strip every organ from children who died at Alder Hey hospital in Liverpool, frequently lying to parents and falsifying medical records.

A separate report highlighting the scale of the organ scandal in other parts of the NHS, revealed that more than 100,000 body parts have been stockpiled in other UK hospitals - many without the consent of relatives and most of which have never been used for

"Those who did wrong will now be held to account. The pain caused to the parents by this dreadful sequence of events is unforgivable."

Alan Milburn
Use of tissues collected for clinical reasons

- Superfluous tissue left after its clinical purpose has been fulfilled can be a valuable research resource. The commonest example is the use of archived sera collected primarily for diagnostic purposes and when, at the time of collection research was not envisaged, nor was consent given. Providing samples can be securely anonymised, subsequent use may not pose ethical questions. However, this will depend on what the research tests seek to find. The tests may identify information of clinical relevance which should be disclosed to the owner. Consequently, it is advisable to include in consent forms the agreement to the use of superfluous tissue or serum, and acknowledge that any information subsequently deemed to be of clinical relevance would be disclosed to the owner.

- The collection of either a significantly greater quantity of tissue, or additional types of tissue (say, during surgery) than is strictly required for diagnostic or treatment purposes requires ethical review. Licence authorities under ASPA may also be required if the additional intervention are such that, of themselves, they may cause pain, suffering, distress or lasting harm.

Archived and *post-mortem* material

- Ethical committee oversight not currently required by this journal: the study was performed on archived material collected previously during clinical procedures. Explicit owner informed consent for participation in this study was not stated.

- Ethical committee oversight not currently required by this journal: the study was performed on material collected during post-mortem examination. Explicit owner informed consent for participation in this study was not stated but general permission for post-mortem examination was given.
Equine specific considerations

• Food producing animal
  – At time of death, abattoir owns animal
    • "Ethical committee oversight not currently required by this journal: the study was performed on material obtained from an abattoir."

• US Donation programmes with tax benefits
  – at time of study, institute owns animal but a research waiver has been signed by the previous owner
    • "Explicit owner informed consent for participation in this study was not stated but general permission for post-mortem examination was given."
Equine-specific considerations

• Sports and racehorses are a passion, commodity, hobby and/or business
  – Owner will usually have given authority to act to trainer or manager
    » does this include informed consent for participation in research?
  – Racing and sporting authority databases available to public documenting outcomes
  – Racing and sporting authorities impose mandatory clinical assessments (pre and intra-competition, specific studies)
Racing and Sporting Authorities can impose specific studies on competitors publish information that can be used for research

**Analytical Clinical Studies**

Horse-, rider-, venue- and environment-related risk factors for elimination from Fédération Equestre Internationale endurance rides due to lameness and metabolic reasons

**Ethical animal research**

A. Nagy, J. K. Murray, S. J. Dyson

Ethical review not required by this journal: retrospective analysis of outcome data in the public domain.

**General Article**

**Occurrence of cardiac arrhythmias in Standardbred racehorses**

J. Slack*, R. C. Boston, L. R. Soma and V. B. Reef

DOI: 10.1111/evj.12299

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**Ethical Animal Research:** The study was approved by and performed in cooperation with Pennsylvania Harness Racing Commission at Chester Downs and the Meadows Standardbred Horseman’s Association. Trainers gave permission for additional 24 hour ECG recording in individuals with atrial fibrillation.
Ethical Animal Research
Post mortem examination of all horses that die or are euthanased on Victorian racetracks is mandatory and is funded by Racing Victoria Limited.

Ethical Animal Research
Necropsy records and cadaveric specimens were acquired through the California Horse Racing Board Postmortem Program conducted by the California Animal Health and Food Safety Laboratory System.
Equine-specific considerations

• Breeding is commercial
  – Pedigrees published
    • genetic research may affect siblings/parents in different ownership from individual offering owner informed consent
  – Some breeds are very small and individuals are easily identified from stud books
Equine Veterinary Journal: Recent and future directions

C. M. Marr

It is also incumbent on veterinary journals to ensure that animals used in research are treated humanely and ethically. Experimental research involving animals which is not reported appropriately is unethical regardless of how the animals were treated in the laboratory, and EVJ has now adopted the ARRIVE guidelines: http://www.nc3rs.org.uk/page.asp?id=1357, which have been developed by the National Centre for the Replacement, Refinement & Reduction of Animals in Research to improve standards of reporting and ensure that the data from animal experiments can be fully evaluated and used.

When client-owned animals are used for research, it is imperative that the owners of those animals have given informed consent. In 2010, the International Association of Veterinary Editors produced a consensus statement (http://veteditors.org/ethicsconsensusguidelines.html), and EVJ’s Author Guidelines adhere to this policy. Recognising that national laws and regulations vary, we have added a clause that allows the committee to accommodate researchers who do not have access to this facility. The advantages of ethical review and the importance of owner informed consent were outlined by Professor Joe Bertone in our July 2013 issue [45]. Prospective authors should be aware that EVJ’s editors have resolved that by 2019 we will have achieved a position of zero tolerance and that owner informed consent and ethical committee review and oversight will be essential in a wide range of studies. Detailed and transparent information on how we envisage proceeding to zero tolerance will be provided as we progress along that pathway.
## Proposed specific OIC requirements for client-owned animals by 2019

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<thead>
<tr>
<th>Requirement</th>
<th>Requirement Specificity</th>
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<tbody>
<tr>
<td>Prospective clinical studies?</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-invasive samples from healthy client owned animals?</td>
<td>Yes</td>
</tr>
<tr>
<td>Invasive samples from healthy client owned animals?</td>
<td>Yes, often ASPA</td>
</tr>
<tr>
<td>Retrospective review of clinical records?</td>
<td>Opt out</td>
</tr>
<tr>
<td>Archived images related to the reason the images were obtained?</td>
<td>Opt out</td>
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<tr>
<td>Archived images taken for unrelated reasons?</td>
<td>Opt out</td>
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<tr>
<td>Archived tissue or fluids related to the reason obtained?</td>
<td>Opt out</td>
</tr>
<tr>
<td>i. Not case specific</td>
<td>Opt out</td>
</tr>
<tr>
<td>ii. Case specific</td>
<td>Yes</td>
</tr>
<tr>
<td>Archived tissue or fluids unrelated to the reason obtained?</td>
<td>Opt out</td>
</tr>
<tr>
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<td>Opt out</td>
</tr>
<tr>
<td>ii. Case specific</td>
<td>Yes</td>
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<tr>
<td>Studies involve determining genetic markers?</td>
<td>Yes</td>
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<tr>
<td>Original source of cell lines (e.g. stem cells)?</td>
<td>Yes</td>
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<tr>
<td>Questionnaires§?</td>
<td>Yes</td>
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<tr>
<td>Post-mortem, related to reason PME was performed</td>
<td>Opt out*</td>
</tr>
<tr>
<td>Post-mortem, unrelated to reason PME was performed</td>
<td>Yes</td>
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* except where required by Sporting Authorities or donations, § informal follow up discouraged
Likely to continue to assess on a case-by-case basis....

• Likely to continue to allow "where such a committee does not exist……" option
• In vivo experiments and clinical research: editors must be satisfied that benefit must outweigh cost regardless of status institutional approval
• Unlicensed products in clinical research where ACT or equivalent not required by national authorities
• Telephone follow-up - usually not a questionnaire, replace with "informal follow-up"
• Abattoir and donation studies
• Studies using material from sporting authority mandatory clinical and post-mortem exams
Raising awareness amongst EVJ's authors and readers

• Regular editorial
• Statement of "Ethical Animal Research" in every article, even where "not applicable"
• Presentation at BEVA Congress 2014, with follow-up webinar
IAVE consensus author guidelines 2010

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Reflection

• Implementing IAVE 2010 consensus statement seemed initially a straightforward matter
• The apparent simplicity is a strength
• Must ask specific questions of authors to obtain the information we want
• Cannot rely solely on peer-reviewers if we want consistent appraisal of journal-specific requirements
• Useful to have a multi-disciplinary group to refer to
• On-going process on a pathway to zero tolerance
• Although multiple "rules" are a problem, they are difficult to avoid when seeking to achieve consistent decision-making