Research paper

The Nature and governance of veterinary clinical research conducted in the UK

P. Fordyce[a]* B.Vet.Med. PhD DWEL MRCVS

S. Mullan[b] BVMS PhD DWEL MRCVS

[a] *Department of veterinary Medicine, University of Cambridge, Maddingley Rd, Cambridge CB30ES, UK*

[b]*School of Veterinary Sciences, University of Bristol, Langford House, North Somerset, BS40 5DU, UK*

*Email for correspondence: psf23@cam.ac.uk (Peter Fordyce).

Abstract

In order to quantify the amount of clinical research conducted on client owned animals under the Veterinary Surgeons Act 1966, and the nature and extent of any ethical review of that research, a questionnaire was sent to six UK veterinary schools, one charity veterinary clinic, and twelve private referral clinics. The questionnaire examined whether, and how much clinical research respondents undertook, and the composition of any ethical review panels examining research proposals. The questionnaire revealed a substantial amount of clinical research was conducted in the UK, with over two hundred veterinary surgeons involved in the year of the survey, with at least one hundred and seventy academic papers involving clinical research published by respondents in the same year. However it proved impossible to quantify the full extent of clinical research in the UK. All UK veterinary schools required ethical review of clinical research. The composition and working practices of their ethical review panels generally reflected skill sets in ethical review panels set up under statute to consider the ethics of non-clinical biomedical

research on animals, and clinical research conducted on human patients. The process for review of clinical research in the private sector was less clear.

Introduction

The importance of 'evidence based medicine' in clinical decision making in veterinary medicine has become increasingly recognised, with clinical research on veterinary patients being central to establishing that evidence base, and publication and dissemination of that evidence key to improving that clinical decision making process (Egenvall 2012; Lanyon 2012; May 2012; Trees 2012; Veterinary Record 2012; Royal College of Veterinary Surgeons undated). However, unlike clinical research on human patients, and provided the clinical research on veterinary patients is conducted as part of 'Recognised Veterinary Practice' (RVP) under the Veterinary Surgeons Act 1966, such research does not have to be subjected to an ethical review process, being exempted from the strictures of the Animals (Scientific Procedures) Act (ASPA) and 63/2010/EU (HMSO 1986; European Union 2010).

Ethical concern about the use of animals for biomedical research has driven UK statute legislation since 1876 (Wolfensohn and Lloyd1988; Kean 1998). The Animals (Scientific Procedures) Act 1986 (ASPA) contains a requirement that before a project is licensed, the Secretary of State must "weigh the likely adverse effects on the animals concerned against the benefit likely to accrue as a result of the program to be specified in the license" (HMSO 1986). The structure of ASPA contains ethical approaches to animal use such as those iterated in the Banner Principles (Banner 1995), the Bateson Cube (Bateson 1986) and Russell and Burch's 'Three Rs'(Russell and Burch 1959) and provides a legal framework in which societal ethical concerns may be addressed, and decision making made accountable. Such statutory accountability for project authorisation has been further reinforced since the EU Directive

63/2010/EU, where ‘moral evaluation of scientific validity’ of such research has become a statutory requirement across the EU.

The history of the use of human patients for biomedical research by their physicians has been well documented, as are the ethical dilemmas associated with such use (Sereny 1974; Kean 1998; Mason and McCall Smith 2006), such ethical concerns leading to legislation at UK and European level to regulate the use of human patients for clinical research by medical practitioners. In particular, there is a statutory requirement for ethical review of such research, and statutory requirements for the working practices and membership profiles of these ethical review panels (Department of Health 2011; Privireal-UK undated).

While there is no statutory requirement for ethical review of veterinary clinical research conducted as part of recognised veterinary practice, evidence of ethical review is increasingly required by funding bodies and publishers (International Association of Veterinary Editors 2010; NC3Rs 2010; 2013). Additionally, the potential for ethical concern by owners about the use of their animals in such research is recognised (Rollin 2006; Yeates and others 2013), and if, as Porter put it, “the primary purpose of the [Veterinary Surgeons’]Act is to protect animals and their owners against unqualified, incompetent or unethical practitioners" (Porter 1990), the profession’s arrangements to ensure that such research is ‘ethical’ are likely to come under examination.

This paper presents the findings of the first survey into the extent of clinical research conducted under the Veterinary Surgeons’ Act (VSA)1966, and the extent and nature of any ethical review that research was subjected to. The study was conducted at the time the Royal College of Veterinary Surgeons and the British Veterinary Association convened a working party to provide

advice and guidance to the profession on 'ethical review of clinical research', with the aim of "promoting best practice and protecting the profession, the public and the animals they own".

Materials and methods

In order to establish the extent of clinical research conducted under the Veterinary Surgeons Act (1966) in the UK (referred to subsequently as 'clinical research'), seven UK veterinary schools, one large charitable veterinary organisation with clinics, 12 private referral clinics (seven small animal and five equine) where RCVS or European diploma holders worked, and two large farm animal practices advertising 'intern' posts were initially contacted during 2012. The organisations which confirmed that they conducted clinical research were sent a letter and questionnaire. The veterinary schools and charity were sent the complete questionnaire and the private referral veterinary clinics were sent a shortened version in order to maximise the response rate. The questionnaire was sent to the chairperson of the ethical review panel (ERP) of the veterinary schools and charity, and to the senior partner/clinician or practice manager of the private referral clinics. If organisations had not replied to the first request to complete a questionnaire, a second request was made approximately one month later.

The letter accompanying the questionnaire suggested a working definition of 'clinical research', with an option for respondents to provide their own definition; the working definition of clinical research suggested in the letter was:-

"Studies on client or institution owned animals conducted within the remit of 'accepted veterinary practice' under the Veterinary Surgeons Act 1966, to generate generalisable new

knowledge by collecting evidence to refute or support or develop a hypothesis with regard to diagnosis, prognosis or treatment".

The questionnaire was divided into seven sections encompassing the nature of the organization and the clinical research they conduct, details of their ERP and ethical review process including the resources available to applicants and areas of concern they commonly considered. The full questionnaire can be found in the Supplementary material.

Results

Overview of clinical research conducted in the UK

The questionnaire achieved a response rate of 68%, with fifteen of the twenty-two organisations contacted completing the long or short version of the questionnaire. All seven veterinary schools and the charity responded to the survey, (hence forth referred to as 'the institutions'), with either the chairperson providing data (3/8) or another member of the ERP doing so (5/8). Six of the seven small animal referral clinics contacted reported that they conducted clinical research, five of which replied in full to the short questionnaire, data being provided by the senior partner/clinician for four clinics, and the practice manager for the fifth. Four of the five equine clinics reported that they conducted clinical research, with the senior partner/clinician from two replying to the short questionnaire. Of the farm animal practices, one replied that while they conducted 'clinical audit' they felt very little of their work could be construed as 'clinical research'; the second practice did not reply. In order to preserve the anonymity of the charity, their results have been included with those from the veterinary schools.

Only six of the eight institutions surveyed provided data about the number of veterinary surgeons involved in 'clinical research', but for the fifteen organisations who did, the survey revealed 201 veterinary surgeons had been conducting clinical research in the previous year. Data were not available from the small animal private referral clinics about the number of clinical research projects subjected to ethical review in the previous year, but for the six institutions who provided data, and the two private equine practices, the total was 197 projects. Data on the number of papers based on clinical research published is similarly incomplete (3/8 for the 'institutions', none for the equine clinics), but at least 171 papers were published (see Table 1).

The 'institutions', and one of the private referral clinics regarded their remit as a mixture of providing clinical services to clients and research; the remaining six private referral clinics regarded clinical service provision as their main function.

All of the 'institutions' received funding for clinical research from charity and industry, with four additionally receiving funding from government. Three of the five small animal private referral clinics had received funding from charitable sources, and one had received funding from industry. Most of the clinical research conducted by the private clinics was funded 'in-house'.

All the organisations conducted post graduate training, with approximately 160 training places reported as involving clinical research in the 'institutions', and 32 places in the five private referral clinics who provided data on this. However, some respondents in the 'institutions' commented that it was difficult to distinguish between PhD studies that might, or might not, involve clinical research. All organisations were involved in veterinary undergraduate teaching through their core curriculum, or extra-mural studies. The eight veterinary institutions had approximately 160 training places involving clinical research between them (mean=20 (range 5-

~55). A total of 32 training places involving clinical research were reported by the private referral clinics (5/7) (mean=6 (range 1-18).

The range of species on which the institutions carried out clinical research varied considerably, (figure 1), with seven of the eight institutions providing data on this. In the case of the private referral clinics, clinical research was only conducted on the species of their speciality (five working with cats and dogs, two with equines).

Ethical review of clinical research in the UK

All of the 'institutions' had an ethical review process for examining clinical research proposals. Two of these institutions also provided an ethical review service for clinical research proposals from veterinary surgeons not working at the institution, one of these providing services for nine outside organisations (with two applications in the last 12 months), and the second providing services to two outside organisations within the last 12 months. A further two of institutions said they may be involved in ethical review of clinical research conducted outside their institution, if members of their staff were involved.

Three of the seven private clinics had an 'in house' ethical review processes for clinical research, a further two using the services of on 'outside' ethical review provider.

Four of the 'institutions' provided a publicly available definition of what they considered constituted clinical research on their web sites, and are reproduced in Supplementary material 2. Several of the private referral clinics commented on the problem of defining clinical research, particularly with respect to distinguishing between clinical audit, case reports, retrospective review of data and prospective studies, and at what point (and at what level) ethical review of such clinical research was appropriate. None had a publicly available definition of what they

158 considered clinical research to be, but all stated that they interpreted ‘clinical research’ to mean
159 something similar to the definition suggested in the questionnaire.
160
161 *Membership profiles of the clinical research Ethical Review Panels*
162 The Ethical Review Panels (ERPs) of the eight institutions were established between 1990 and
163 2011, all having a mixture of males and females, veterinary surgeons and non-veterinarians (see
164 Table 2).
165 The most common skill set was someone holding a ‘bioscience-based PhD’ (8/8), followed by
166 members holding a personal or project license under ASPA 1986 (7/8); these members may or
167 may not have additionally held a MRCVS. Six panels had members who were currently Named
168 Veterinary Surgeons, with two ERPs having members who had worked as NVSs in the past: at
169 least four ERPs contained members holding a RCVS Certificate or Diploma in Laboratory
170 Animal Science. Two ERPs had members holding a RCVS Certificate in Animal Welfare
171 Science, Ethics and Law. Six ERPs had members with RCVS or European level diploma status
172 in other clinical specialties.
173 Members of the ERPs who were not MsRCVS included, statisticians (4 ERPs), ‘ethicists’ (3
174 ERPs), veterinary nurses (3 ERPs) and a medical doctor (1 ERP). ‘Lay members’ were present
175 on five ERPs, although only one used the services of lay persons not connected to the institution.
176 The relative compositions by ‘skill set’ of the various ERPs can be found in the supplementary
177 material.
178 .
179 Two of the eight institutions had members of their clinical research ERPs serving on similar
180 panels outside their institution. The most common ERPs that members of the clinical research

ERPs additionally served on were Local Ethical Review Panels (LERPs) (now Animal Welfare and Ethical Review Bodies- AWERBs) set up under ASPA (1986) (4/7 respondents), followed by the RCVS 'Recognised Veterinary Practice' Committee (2/7 respondents). Two organisations did not have any members who had served on any other Ethical Review Panels.

Four of seven institutions reported that they had one member who had served on one of the following committees: Ethical Review Committee set up under Zoo Licensing Act 1981, Medicines for Human Use Review Panel, Animal Procedures Committee, Physical Interventions committee.

Most respondents stated they might not know about the links of members of the clinical research ERPs to 'animal welfare organisations'. However two organisations reported links of members to the RSPCA, four organisations to either the "Laboratory Animal Science Association", " Laboratory Animal Veterinary Association" or the "Institute of Animal Technology", and four to the "Animal Welfare Science, Ethics and Law Veterinary Association". No organisation reported links of panel members to 'Compassion in World Farming', 'People for the Ethical Treatment of Animals', 'British Union for the Abolition of Vivisection' (now 'Cruelty Free International') or 'World Society for the Protection of Animals' (now 'World Animal Protection').

Areas of ethical concern routinely considered by the clinical research ERPs

Only five institutions provided data on issues routinely considered by their ERPs The only issues not routinely considered by all five were 'statistical validity of the model' (4/5), funding/recourses -including conflicts of interest (3/5), 'end point's (2/5), and 'un-blinding' of trials in case of adverse events (2/5), with all five considering the number of animals used, the

scientific quality of the work, ,the harms and risk/benefit to the patient ,and issues surrounding informed consent, data management and regulatory compliance.

Three institutions operated a formal 'interim review process' to highlight any concerns about patient safety that had arisen during the research. Four of the remaining five institutions that did not operate a 'formal interim review' policy commented that 'self- reporting' to the ERP was expected in the event that adverse events occurred during the research. Four institutions had a formal mechanism for retrospective review of clinical research projects.

Procedures and Processes of the clinical research ERPs

All the institutions mandated that any clinical research conducted by the institution must be subject to ethical review, using standard application forms, with all but one providing a web site informing applicants how the ethical review process works. Five of the institutions provided a formal set of guiding principles relating to the ethical use of animals in clinical research via their departmental/university intranet sites; in one case these principles were made available via a publicly accessible web site.

A range of documents/resources that might be useful to applicants to their ethical review process were made available. The most common resource made available was 'Guidance notes on operation of A(SP)A 1986' (5/8 institutions), followed by 'RCVS guidance on interface between A(SP)A 1986 and the VSA 1966', links to the Veterinary Medicines Directorate web site regarding 'Animal Test Certificates', and information on data protection issues (3/8). Texts on 'human clinical research', 'biomedical ethics' and links to EU Directive 2010/63 were mad available in two of the eight institutions.

Seven of the eight institutions used a combination of meetings and e-mail to discuss applications and policy issues relating to ethical review, the eighth only meeting in person to do this. The frequency of meetings varied between institutions; one meeting annually, four bi-annually, two institutions meeting three times per year, and one meeting six times.

Four of the eight institutions had a formal target time by which their ERPs aimed to produce their first comment on a clinical research application; three aiming to comment within 3 weeks, one within a month. The remaining four institutions did not have a formal time scale for first comment, but two said they aimed to respond in 2-3 weeks. Average time to give final approval varied between two weeks and six weeks (2 at 2 weeks, 2 at 3 weeks, one at 5 weeks and 2 at 6 weeks). Five of the eight institutions used a fast track mechanism to facilitate passage of some clinical research proposals.

Three of the institutions made formal training in biomedical ethics available to members of their ERP. All institutions provided the services of a senior scientist to help researchers with experimental design, and seven of the eight institutions additionally provided the services of a statistician.

Discussion

The amount of clinical research in the UK

Overall, the survey revealed a large number of clinicians were involved in clinical research, with over 200 reported in this survey alone, and 197 projects reviewed by ERPs in the year proceeding the survey. The absence of a statutory definition of clinical research, and absence of statutory requirement to record the activity in terms of location, who is doing it, the nature of the research, or to make that information publicly available, may have all confounded the ability to

collect a complete data set. Not all institutions contacted were able to provide full data, and not all individuals or organisations conducting clinical research will have been contacted. Additionally, the number of projects undergoing review reported here (197 in the last 12 months in the institutions surveyed) may not have accurately reflected the number of projects that are eventually authorised, or that started in that year, or more importantly, were still ongoing from previous years. Similarly, while the number of papers published by the institutions in the year of the survey may give an indication of the extent of clinical research conducted by them in previous years, care must be taken in interpreting the significance of the exact numbers given the same concerns about an incomplete data set, the timeframe over which that research was conducted, and the nature of any ethical review that might have considered the proposals at the time they were submitted.

For methodological reasons it proved impossible to obtain data about the actual number of animals involved in clinical research over that period, as the data was not systematically recorded by the respondents. However, in spite of the caveats above, these results show that it was not uncommon for animals visiting both the institutions, and the private referral clinics, to be involved in clinical research. Given the current drive for evidence-based medicine, it seems reasonable to suggest that requests for participation may increase the numbers involved in future

If the above suggestion is accepted, the above findings, along with any future increase in the number of animals involvedmay influence the relationship between the veterinary profession and the animal owning public; the greater the extent of clinical research, the more likely clients may

have their animals exposed to it, and hence the more likely they are to query the professional and legislative arrangements to ensure the use of their animals is ethically acceptable.

As discussed above, it proved impossible to quantify the exact number of animals involved in clinical research in the year preceding the survey, unlike the situation for research conducted under A(SP)A1986. In the same year, the Home Office reported the use of 3,710,621 animals of all species involved in biomedical research protected under that act (HMSO 2011), of which there were 153 cats, 2,865 dogs and 333 horses, i.e. less tha 0.01% of the total. During this period the Home Office reported licensing 564 projects, with 2,624 project licenses 'active' in that year.

Given the problems of assessing the actual number of animals involved in clinical research over the same period, it is difficult to make a strict comparison between the number of animals given 'special protection' under A(SP)A 1986 used for such research, and the number of the same species involved in clinical research. However, given that the institutions reviewed 197 clinical research projects over the same period, and the percentage of projects involving cats, dogs and horses that were reviewed by the ERPs, (Figure 1), it is possible that biomedical research was conducted on more animals of these species under the VSA 1966, than under A(SP)A 1986.

Clearly the nature of, and motivation behind, the research conducted under the two acts may be different. However, given the inference from the nature of the way A(SP)A 1986 has been drafted (i.e. that society places greater importance on the welfare of species given special protection under Section 5(6) of A(SP)A 1986), should more animals of these species be involved in 'clinical research' than research conducted under A(SP)A1986, it seems reasonable to suggest that society (or it's representatives) may take a close interests in the profession's arrangements to ensure such research is ethical.

The extent and nature of clinical review of ethical research

The questionnaire aimed to determine whether the membership and working practices of Ethical Review Panels (ERPs) would be likely to engender confidence that clinical research was subject to appropriate ethical scrutiny. The subsequently published RCVS/BVA report (RCVS/BVA 2013) examining ethical review for practice-based clinical research asserted that "Going through a process of external ethical scrutiny provides assurance that ethical issues have been carefully assessed". The "Governance Arrangements for Research Ethics Committees" that provides statutory guidelines for clinical research conducted on human patients states ethical review should be "competent, timely and authoritative" (Department of Health 2011). While there was some variation in approach, the ERPs' working practices appeared likely to deliver proportionate review in a timely manner, addressing issues of scientific design, appropriate legislative oversight, and issues relating to patient welfare and informed client involvement.

It seems reasonable to suggest that the competence and authority of the output from ethical review will be dependent on the membership's skill sets; the Federation of European Laboratory Animal Science Associations working group examining ethical review in non-clinical biomedical research on animals concluded "Confidence in ethical judgements largely depends on the approach of those who make them: that is, on whether the process of review is seen to result in sensitive, balanced and informed decisions and judgements that are responsive to reasonable perspectives on the issue". (Smith and others 2007). Similarly, the RSPCA/LASA "Guiding principles on Good Practice for Ethical Review Processes" (RSPCA & LASA 2010) suggests that "involving the right mix of participants in the ethical review process is integral to its success", as are their "key competencies" and "personal qualities". For methodological reasons it is impossible to discuss whether outputs from the seven institutional ERPs actually do "result in sensitive, balanced and informed decisions and judgements". However, by comparing the

membership profiles of the clinical research ERPs with those of ERPs that deal with similar ethical issues, and whose membership is mandated in statute, (e.g. those involved with ethical review of human clinical research, and non-clinical biomedical research on animals in the UK, Europe and other jurisdictions), it may be possible to infer whether society might consider the membership of the clinical research ERPs revealed here likely to be 'fit for purpose'.

All ERPs contained members trained in scientific method (PhD level). Inclusion of RCVS/European diplomats in 6/8 panels is likely to have brought additional clinical expertise and perspective. Half of the panels containing statisticians, while nearly all made the services of a statistician available to applicants. Inclusion of Named Veterinary Surgeons in six of the eight panels is also pertinent scrutiny of study design, given their role in assessing scientific validity in the context of 'welfare harm- benefit analysis' in LERPs (AWERBs).

Named Veterinary Surgeons would additionally bring specific knowledge of the legal frameworks applicable to the proposed research, as would experience of serving on the 'RCVS-RVP' committee (2 panels), and the presence of members with RCVS Certificate in Welfare Science, Ethics and Law (2 panels). Similarly, given that law relating to research forms part of the mandatory training for personal and project licence holders under ASPA1986 members holding such licenses (7/8 panels) should have some knowledge of this area (HMSO 2000, 2014).

In relation to ethical assessment of projects, the finding that five of the eight respondents had at least one member of their review panel with formal training in ethics was reassuring. Additionally, of the remaining three institutions, two had members with RCVS Certificates or RCVS/European diplomas in Laboratory Animal Science, where post graduate level study of ethics forms part of that training (RCVS undated; European Society for Laboratory Animal

340 Veterinarians undated). The requirement for training in ethics for Named Veterinary Surgeons
341 (HMSO 2014) and licence holders under ASPA1986 similarly suggests panels containing such
342 members would have some knowledge of ethical issues associated with animal research.
343 The number of panels without 'lay members', (3/8), particularly the number with no affiliation to
344 the organisation (7/8), was surprising given Rose and Grant's assertion that "ethical questions are
345 matters for society as a whole, and are not the prerogative of the scientific community", (Rose
346 and Grant 2013). This finding may reflect a view that the RCVS Guidance on recognised
347 veterinary practice makes a clear distinction between research where the purpose of the
348 intervention is for the benefit of the patient (clinical research), and research conducted under
349 ASPA1986, (where it is not), and hence 'lay oversight' is not perceived as a significant issue.
350 However, clinical research and the use of novel therapies raise their own ethical dilemmas within
351 the remit of RVP, e.g. Rollin 2006; RCVS/BVA 2013; Yeates, and others 2013, and the statutory
352 guidance for human clinical research also seems pertinent. Such guidance suggests at least one
353 third of the membership of human research ethics Committees should be 'lay', so outputs will
354 "reflect the currency of public opinion", (Department of Health 2011). Such a requirement may
355 suggest wider lay participation in ethical review would be helpful in providing further public
356 reassurance about veterinary clinical research.
357 While the caveat about 'lay membership' must apply, given the above arguments, and the
358 similarities between the composition of the ERPs reported here and ERPs mandated in statute for
359 examining the ethics of biomedical research in related areas the survey would suggest that the
360 mix of competencies brought to the clinical research ERPs by their members might reasonably
361 beexpected to generate "sensitive, balanced and informed decisions and judgements".
362

Conclusion

A significant number of veterinary surgeons were involved in clinical research during the survey year and much of that research was performed on cats, dogs and horses. The details of the composition and working practices of the Ethical Review Panels (ERPs) of the institutions revealed that most had members with skill sets reflecting those in ERPs set up under statute to consider ethical issues associated with non-clinical biomedical research on animals, and clinical research on human patients. Hence it seems reasonable to suggest clinical research in these organisations will be conducted with appropriate legal protection, and with the ethical issues associated with the research having been considered by people with the appropriate knowledge. It is harder to comment on the position for clinical research conducted outside the institutions examined. While the RCVS/BVA report published since the survey (RCVS/BVA 2013) has brought some much welcome clarity, the lack of a statutory or professional regulatory requirement to subject it to ethical review, or as in the case for clinical research on human patients, ensure the composition of any ERPs doing such review "allow for a sufficiently broad range of experience and expertise so the rationale, aims and objectives and design of the research proposal can effectively be reconciled with the dignity, rights and safety of the people who take part" (Department of Health 2011), makes commenting on whether the Veterinary Surgeons Act1966 currently provides sufficient protection for all patients and their owners difficult. Unlike clinical research on human patients, and non-clinical biomedical research on animals, lack of registration of the activity precludes obtaining a complete data set for where the research is happening; hence the ability to scrutinise whether any ethical review of the activity is appropriate is impossible.

The recent establishment of an ERP by the RCVS (RCVS 2016) to consider proposals for clinical research from practitioners who lack access to ethical review seems likely to provide a mechanism to help reassure owners, the electorate, funders of research and publishers that "the public can have confidence in, and benefit from, high quality, ethical research" (Department of Health 2011), for research proposals reviewed by that body. Similarly, the 2013 RCVS/BVA report provides guidance on the nature of any clinical research proposals that may warrant ethical review at that level. However there might also be some benefit in the profession's regulatory body considering producing regulatory guidelines mandating what types of clinical research must be subjected to ethical review by an ERP, and requirements for the registration and composition of ERPs to conduct it.

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TABLE 1: Number of veterinary surgeons providing clinical services, conducting clinical research, the number of clinical research papers published, and number of post graduate training places involving clinical research, in the 12 months preceding the survey in 2012

	Type of organization (total (mean (range))			
	Veterinary schools and charity (n=6/8)	Small animal private referral clinic (n=5/5)	Equine private referral clinic (n=2)	**Total**
Approx. number of veterinary surgeons providing clinical services	286 (48 (20-100))	110 (22 (10-36))	23 (12 (8-15))	**419**
Approx. number of veterinary surgeons conducting clinical research in the last year	142 (24 (9-57))	53 (11 (5-21))	4 (n=1)	**201**
Number of clinical research projects subject to Ethical Review in the last year	193 (32 (14-51))	Not provided	4 (n=1)	**197**
Number of papers published in the last year relating to clinical research	119 (40(14-90)) (n=3)	52 (10 (5-20))	Not provided	**171**
Approximate number of post graduate training places involving clinical research	160 (27 (5-~55))	32 (6 (1-18))	Not provided	**192**

TABLE 2: Year of establishment, size and composition of the clinical research Ethical Review Panels within the 'institutions'.

	Institution number							
	1	2	3	4	5	6	7	8
Year established ERP for clinical research	2011	NP	NP	2000	2003	1990	2003	2008
Composition of the Ethical Review Panel								
Status of chairperson in the organisation #	Lec	Prof	Ind	Prof	RF	SLec	HoD	HoD
Number of people	5	9	21*	8	7	9	9	6
Male	2	6	11	4	4	7	8	0
Female	3	3	10	4	3	2	2	6
Number of veterinary surgeons	4	5	11	6	6	9	2	4
Quorum requirements for decision-making?	n	y	n.g.	n.g.	y	n	y	y

NP = Not Provided

Status of chairperson within the organisation; abbreviations used:-

Lec, lecturer: Prof, Professor: Ind, Independent of organisation: RF, Research Fellow: SLec, Senior lecturer: HoD, Head of Department.

present in university ERP, not departmental ERP

***** Size of the ERP is sometimes expanded by another 5 people (4 Female, 1 Male) if the workload of the panel is high.

? Chairperson of ERP uncertain of the answer