



Fordyce, P., & Mullan, S. (2017). Nature and governance of veterinary clinical research conducted in the UK. *Veterinary Record, In Practice*, 180(3), [69]. DOI: 10.1136/vr.103808

Peer reviewed version

Link to published version (if available):
[10.1136/vr.103808](https://doi.org/10.1136/vr.103808)

[Link to publication record in Explore Bristol Research](#)
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1 **Research paper**

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

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10

11 **Abstract**

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

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

26 **Introduction**

27 The importance of ‘evidence based medicine’ in clinical decision making in veterinary medicine
28 has become increasingly recognised, with clinical research on veterinary patients being central to
29 establishing that evidence base, and publication and dissemination of that evidence key to
30 improving that clinical decision making process (Egenvall 2012; Lanyon 2012; May 2012; Trees
31 2012; Veterinary Record 2012; Royal College of Veterinary Surgeons undated). However,
32 unlike clinical research on human patients, and provided the clinical research on veterinary
33 patients is conducted as part of ‘Recognised Veterinary Practice’ (RVP) under the Veterinary
34 Surgeons Act 1966, such research does not have to be subjected to an ethical review process,
35 being exempted from the strictures of the Animals (Scientific Procedures) Act (ASPA) and
36 63/2010/EU (HMSO 1986; European Union 2010).

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

47 63/2010/EU, where ‘moral evaluation of scientific validity’ of such research has become a
48 statutory requirement across the EU.

49 The history of the use of human patients for biomedical research by their physicians has been
50 well documented, as are the ethical dilemmas associated with such use (Sereny 1974; Kean
51 1998; Mason and McCall Smith 2006), such ethical concerns leading to legislation at UK and
52 European level to regulate the use of human patients for clinical research by medical
53 practitioners. In particular, there is a statutory requirement for ethical review of such research,
54 and statutory requirements for the working practices and membership profiles of these ethical
55 review panels (Department of Health 2011; Privireal-UK undated).

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

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

69 advice and guidance to the profession on ‘ethical review of clinical research’, with the aim of
70 “promoting best practice and protecting the profession, the public and the animals they own”.

71

72 **Materials and methods**

73 In order to establish the extent of clinical research conducted under the Veterinary Surgeons Act
74 (1966) in the UK (referred to subsequently as ‘clinical research’), seven UK veterinary schools,
75 one large charitable veterinary organisation with clinics, 12 private referral clinics (seven small
76 animal and five equine) where RCVS or European diploma holders worked, and two large farm
77 animal practices advertising ‘intern’ posts were initially contacted during 2012. The
78 organisations which confirmed that they conducted clinical research were sent a letter and
79 questionnaire. The veterinary schools and charity were sent the complete questionnaire and the
80 private referral veterinary clinics were sent a shortened version in order to maximise the response
81 rate. The questionnaire was sent to the chairperson of the ethical review panel (ERP) of the
82 veterinary schools and charity, and to the senior partner/clinician or practice manager of the
83 private referral clinics. If organisations had not replied to the first request to complete a
84 questionnaire, a second request was made approximately one month later.

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

88

89 “Studies on client or institution owned animals conducted within the remit of ‘accepted
90 veterinary practice’ under the Veterinary Surgeons Act 1966, to generate generalisable new

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

93

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

98

99 **Results**

100 *Overview of clinical research conducted in the UK*

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

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

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

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

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

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

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

141

142 *Ethical review of clinical research in the UK*

143 All of the 'institutions' had an ethical review process for examining clinical research proposals.

144 Two of these institutions also provided an ethical review service for clinical research proposals

145 from veterinary surgeons not working at the institution, one of these providing services for nine

146 outside organisations (with two applications in the last 12 months), and the second providing

147 services to two outside organisations within the last 12 months. A further two of institutions said

148 they may be involved in ethical review of clinical research conducted outside their institution, if

149 members of their staff were involved.

150 Three of the seven private clinics had an 'in house' ethical review processes for clinical research,

151 a further two using the services of an 'outside' ethical review provider.

152 Four of the 'institutions' provided a publicly available definition of what they considered

153 constituted clinical research on their web sites, and are reproduced in Supplementary material 2.

154 Several of the private referral clinics commented on the problem of defining clinical research,

155 particularly with respect to distinguishing between clinical audit, case reports, retrospective

156 review of data and prospective studies, and at what point (and at what level) ethical review of

157 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

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

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

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

197

198 *Areas of ethical concern routinely considered by the clinical research ERPs*

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

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

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

210

211 *Procedures and Processes of the clinical research ERPs*

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

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

225 Seven of the eight institutions used a combination of meetings and e-mail to discuss
226 applications and policy issues relating to ethical review, the eighth only meeting in person to do
227 this. The frequency of meetings varied between institutions; one meeting annually, four bi-
228 annually, two institutions meeting three times per year, and one meeting six times.
229 Four of the eight institutions had a formal target time by which their ERPs aimed to produce
230 their first comment on a clinical research application; three aiming to comment within 3 weeks,
231 one within a month. The remaining four institutions did not have a formal time scale for first
232 comment, but two said they aimed to respond in 2-3 weeks. Average time to give final approval
233 varied between two weeks and six weeks (2 at 2 weeks, 2 at 3 weeks, one at 5 weeks and 2 at 6
234 weeks). Five of the eight institutions used a fast track mechanism to facilitate passage of some
235 clinical research proposals.
236 Three of the institutions made formal training in biomedical ethics available to members of their
237 ERP. All institutions provided the services of a senior scientist to help researchers with
238 experimental design, and seven of the eight institutions additionally provided the services of a
239 statistician.

240

241 **Discussion**

242 *The amount of clinical research in the UK*

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

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

259

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

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

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

272 As discussed above, it proved impossible to quantify the exact number of animals involved in
273 clinical research in the year preceding the survey, unlike the situation for research conducted
274 under A(SP)A1986. In the same year, the Home Office reported the use of 3,710,621 animals of
275 all species involved in biomedical research protected under that act (HMSO 2011), of which there were
276 153 cats, 2,865 dogs and 333 horses, i.e. less than 0.01% of the total. During this period the Home Office
277 reported licensing 564 projects, with 2,624 project licenses 'active' in that year.

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

285 Clearly the nature of, and motivation behind, the research conducted under the two acts may be
286 different. However, given the inference from the nature of the way A(SP)A 1986 has been drafted (i.e.
287 that society places greater importance on the welfare of species given special protection under Section
288 5(6) of A(SP)A 1986), should more animals of these species be involved in 'clinical research' than
289 research conducted under A(SP)A1986, it seems reasonable to suggest that society (or its
290 representatives) may take a close interest in the profession's arrangements to ensure such research is
291 ethical.

292

293 *The extent and nature of clinical review of ethical research*

294 The questionnaire aimed to determine whether the membership and working practices of Ethical
295 Review Panels (ERPs) would be likely to engender confidence that clinical research was subject
296 to appropriate ethical scrutiny. The subsequently published RCVS/BVA report (RCVS/BVA
297 2013) examining ethical review for practice-based clinical research asserted that “Going through
298 a process of external ethical scrutiny provides assurance that ethical issues have been carefully
299 assessed”. The “Governance Arrangements for Research Ethics Committees” that provides
300 statutory guidelines for clinical research conducted on human patients states ethical review
301 should be “competent, timely and authoritative” (Department of Health 2011). While there was
302 some variation in approach, the ERPs’ working practices appeared likely to deliver proportionate
303 review in a timely manner, addressing issues of scientific design, appropriate legislative
304 oversight, and issues relating to patient welfare and informed client involvement.

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

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

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

328 Named Veterinary Surgeons would additionally bring specific knowledge of the legal
329 frameworks applicable to the proposed research, as would experience of serving on the ‘RCVS-
330 RVP’ committee (2 panels), and the presence of members with RCVS Certificate in Welfare
331 Science, Ethics and Law (2 panels). Similarly, given that law relating to research forms part of
332 the mandatory training for personal and project licence holders under ASPA1986 members
333 holding such licenses (7/8 panels) should have some knowledge of this area (HMSO 2000,
334 2014).

335 In relation to ethical assessment of projects, the finding that five of the eight respondents had at
336 least one member of their review panel with formal training in ethics was reassuring.

337 Additionally, of the remaining three institutions, two had members with RCVS Certificates or
338 RCVS/European diplomas in Laboratory Animal Science, where post graduate level study of
339 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 be expected to generate “sensitive, balanced and informed decisions and judgements”.

362

363 **Conclusion**

364 A significant number of veterinary surgeons were involved in clinical research during the survey
365 year and much of that research was performed on cats, dogs and horses. The details of the
366 composition and working practices of the Ethical Review Panels (ERPs) of the institutions
367 revealed that most had members with skill sets reflecting those in ERPs set up under statute to
368 consider ethical issues associated with non-clinical biomedical research on animals, and clinical
369 research on human patients. Hence it seems reasonable to suggest clinical research in these
370 organisations will be conducted with appropriate legal protection, and with the ethical issues
371 associated with the research having been considered by people with the appropriate knowledge.
372 It is harder to comment on the position for clinical research conducted outside the institutions
373 examined. While the RCVS/BVA report published since the survey (RCVS/BVA 2013) has
374 brought some much welcome clarity, the lack of a statutory or professional regulatory
375 requirement to subject it to ethical review, or as in the case for clinical research on human
376 patients, ensure the composition of any ERPs doing such review “allow for a sufficiently broad
377 range of experience and expertise so the rationale, aims and objectives and design of the research
378 proposal can effectively be reconciled with the dignity, rights and safety of the people who take
379 part” (Department of Health 2011), makes commenting on whether the Veterinary Surgeons
380 Act 1966 currently provides sufficient protection for all patients and their owners difficult. Unlike
381 clinical research on human patients, and non-clinical biomedical research on animals, lack of
382 registration of the activity precludes obtaining a complete data set for where the research is
383 happening; hence the ability to scrutinise whether any ethical review of the activity is appropriate
384 is impossible.

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

395

396 **Acknowledgements**

397 The authors would like to thank the chairpersons of the ethical review panels of all the
398 institutions who responded to the survey, as well as the principals and partners of the various
399 private referral practices for their generosity with their time, and patience and kindness in
400 clarifying issues that were raised by the questionnaire.

401

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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)))			Total
	Veterinary schools and charity (n=6/8)	Small animal private referral clinic (n=5/5)	Equine private referral clinic (n=2)	
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

