RCVS Ethics Review Panel (ERP) Guidance on Multicentre Studies in Clinical Veterinary Research

Clinical veterinary research may involve other centres in the UK or from outside the UK. The reasons may be to increase the number of subjects in a study as well as to advance the science with diagnostic methodology not available in the UK. These are collectively called multicentre studies that will have a **'lead centre'**, and **'secondary centres'** that are part of the collaborative study. However, this raises a number of issues that need to be considered when applying for ethics approval.

If you are applying to the RCVS for ethics approval for a study which already has ethics approval from another institution, e.g., for a multicentre study, please append a copy of relevant approved documents your RCVS application.

The aim of the guidelines is to help applicants provide the necessary information to the RCVS Ethics Review Panel.

1. What counts as a multicentre study?

For the purposes of ethics review, a multicentre study is considered to be a study where data are collected from more than one veterinary practice. For this purpose, a veterinary practice may include multiple sites (e.g., branch surgeries) but not veterinary surgeries working together as part of a practice group.

However, if the practices participating in the study are all part of the same practice group this should be noted on the application form as this may have implications in terms of data transfer – see below.

2. Participating practices

In a multicentre study the relationship between the participating practices and principal researcher could be that of co-applicants or collaborators.

For the purposes of ethics review a **co-applicant** is someone who has had input into the design of the study and is likely to be a co-author of the paper. Co-applicants should be listed on the application form, giving details of the practice from which they will be contributing data, and should sign the application form.

Collaborators can contribute to the research through the recruitment of cases and collection of data or samples. In these cases, an information sheet should be provided for participating practices that provides sufficient information to enable them to fully describe the aims of the study, to recruit appropriate cases and to detail the data or samples that are to be collected and submitted. This information sheet should be appended to the application in addition to the client information sheet.

Where participating practices have already been identified at the time that the application for ethics approval is submitted, written confirmation should be provided from the practice principle/senior veterinary surgeon or collaborator that confirms their understanding of the requirements for participating, and willingness to participate as detailed in the application.

Where participating practices have yet to be recruited, a pro-forma that participating practices will be asked to complete should be appended to the application. The exact details of the information contained will vary between studies but is likely to include:

- Details of participating practice including primary contact
- Details of what information or samples the participating practice will be expected to provide

- Statement of confirmation of understanding of the study
- Statement of confirmation of agreement to adhere to data protection requirements and name of designated data controller.

It is important that the participating practices have copies of the approved application protocols and any subsequent amendments. Providing these is the responsibility of the Lead Applicant/Principal Researcher.

3. Data Collection

We recommend that there should be a Named Data Controller in each participating practice who will be responsible for ensuring that the practice has permission from owners to contribute the required personal data or samples, and who will be is responsible for compliance with data protection and other regulations or legislation or guidelines. In most cases this will involve the removal of any client personal data before submission and, where this is not the case, inclusion of justification for sharing this personal data.

If the Named Data Controller is not the same as the collaborator signing the participation form, they should also be asked to sign.

To ensure that any data collected and submitted is in a comparable format that meets the requirements of the study, we recommend that a standard data collection sheet or form is used. A copy of this form and the method of submission should be included with the application for ethics approval.

4. Informed consent

It is important that any information relating to the owner/keeper continues to be protected, and that informed consent is obtained at the same standard in all centres. The consent form and information sheets for the participating practices should mirror those approved for the lead centre.

It should be remembered that while practices that are part of the same group may be treated as the same legal entity for data protection purposes, clients may not be aware or fully understand the implications of this. Therefore, client information sheets should make clear that the study involves multiple practices, how the data collected as part of the study will be handled (e.g., storage, anonymisation, etc) and who will have access to it.

5. Multicentre studies across different countries and jurisdictions*

Where the lead centre is in the UK but participating practices are overseas, it is expected the that conduct of all researchers meet RCVS requirements as set out in the Code of Professional Conduct and supporting guidance.

Where applications are submitted from outside the UK, or the participating practice are outside of the UK, the principal researcher should provide confirmation that the study complies with any legal and ethical requirements in their own country.

In order to ensure compliance with the RCVS Code of Professional Conduct at least one applicant must be a MRCVS.

Regardless of the country in which the lead centre is based, any application considered for approval by the RCVS Ethics Review Panel will be judged against the legal and ethical requirements expected in the UK, and any pertinent legislation regarding the import and export of personal and scientific data.

Applications for multicentre studies across jurisdictions should include details of how the study will meet the requirements for the export or import of personal data, and if applicable, for the import and export of tissues or other samples submitted as part of the study.

Where a UK practice is applying to the RCVS ERP for approval to participate in an overseas study, their application should be accompanied by a copy of the approved protocol from the country in which the study is based. Where this documentation is not in English the applicant should provide a certified translation.

*Please also cross refer to the RCVS Ethical Review Panel (ERP) Guidance on research and personal data