RCVS Ethics Review Panel (ERP) Guidance on Informed Consent for Clinical Veterinary Research

This guidance is designed to ensure that researchers obtain consent that is **informed**, **voluntary** and **valid** from potential research participants. You can find sample consent forms attached to this page for the use of data, as well as for a prospective study.

Terminology

- **Informed** consent means that participants have been given sufficient information about the proposed research to enable them to balance risks and benefits and decide whether to participate or not;
- **Voluntary** informed consent means that participants have not been coerced into taking part;
- **Valid** informed consent means that participants are able to give consent for their own participation or on behalf of their animals, i.e., they are able to understand, interpret and weigh the information and to make and convey a decision about their participation.

Informed consent for a prospective research study

Information sheet

A critical aspect of informed consent is the offering of sufficient information. In a prospective research study this can be achieved by using an Information Sheet to accompany the Consent Form. The Information Sheet is a separate document describing the study for participants (e.g., owners, veterinary surgeons etc). It should include:

- The details of the research study, in suitable language for the intended participants (see guidance on information sheets – this would normally be in 'lay language').
- All aspects of the study, for example, how personal information will be collected and used.
- An explanation to clients of what exactly will happen to their animal(s) so that they understand the key points for which they are consenting.
- A statement outlining the risks and benefits of participation.
- The names and contact details for those persons who can provide further details if required.

Consent form

The consent form itself should provide a brief summary of the proposed study and should detail the individual points for which consent is being sought, with the option to select yes or no to indicate their consent to each point.

Voluntary informed consent is the norm, with potential participants given adequate time to review the information, reflect on it, and formulate any questions they may have. The person seeking consent should be satisfied that the person giving consent has capacity to understand the information and to make and convey their decision. Participants should be given copies of both the information sheet and the consent form to keep.

For consent to be 'voluntary', there should be no undue pressure put on potential participants to take part, and clear guidance on when and how withdrawal is possible (for example, up until data are

anonymised). The offering of financial incentives to participate is considered coercive and as such the consent may not be voluntary. Pressure to participate may be implied if the researcher is also the clinician who is responsible for their animal's care. A clear statement that refusal to participate in the research study will have no effect on clinical care for any of their animals either now or in the future should be placed in both the information sheet and the consent form, as in the example form provided on this page.

Questions and answers about consent to research participation

When do I need consent for use of data?

Legally, under the UK Data Protection Act 2021, the use of completely anonymised data does not require specific consent (see guidance on data handling). However, ethically, out of respect for our clients, and in the spirit of encouraging openness in research, we should try at least to inform clients that we may use their animals' data in this way, and give them an opportunity to opt-in to such use. However, if you are contacting clients individually, (for example, for follow-up data) then ethically, it is good practice to seek specific informed consent.

Who can give consent for research participation?

If the research involves animals, then the legally competent owner or keeper of the animal(s) is the appropriate person to give consent for their participation (or anyone that the owner has given permission to make decisions about the animals, e.g., a relative, a farm manager). The person giving consent must be at least 18 years of age (required for contract law in England, rather than a specific research requirement), and should have the capacity to understand the information being given to them, to weigh it up, to make a decision and to convey that decision.

What if my research only involves humans, not animals?

You need to receive specific and voluntary informed consent from all potential participants. You need to inform them what personal data you will be collecting from them, and how you will store, use and protect that data, including when the data will be destroyed and who will have access. Only data necessary for the anticipated use must be collected.

What if my research involves other veterinary practices?

If it is a prospective study, then all clients should give specific informed consent, using a participant information sheet and consent form that is standardised for all practices involved. Each practice will also need a named data controller who will be responsible for data protection and for ensuring that all personal details are removed from the data before sharing. If samples are being shared, then the arrangements for transfer of materials should be clearly stated when seeking consent for retention of samples. For retrospective studies, it is the lead researcher's responsibility to check the adequacy of consent for the use of clinical data, unused samples etc. for each participating practice. For collaborative research involving other veterinarians outside the UK other provisions may apply and the person outside the UK must make sure that all national legislation followed.

Is there any other information that I need to include?

Please refer to the guidance on Information Sheets for areas that need to be included in these. As a minimum for informed consent, clients should be made aware of alternative treatment options and the

major risks for their animals involved in the proposed treatment. We would suggest that there is some evidence of ethics approval included in the information sheet.