Ethical use of veterinary health records in clinical veterinary research (Retrospective reviewing)

General Information

1. When clinical veterinary health records are retrieved for a research project then external ethics review is required (see the RCVS Code of Professional Conduct https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-nurses/supporting-guidance/routine-veterinary-practice §25.14 – 25.19). Veterinary Health Record reviews may also be carried out as part of clinical audit and are part of normal clinical practice. However, when sharing this data beyond the practice, such as in publications or at conferences, it would be prudent to treat this as research and to seek an external ethics review.

2. Carrying out a review of published papers and epidemiological research texts combined with practice clinical records for a research project is an important way to advance evidence-based veterinary medicine. But extracting primary data from practice records raises several important ethical and legal issues which are addressed in this guidance.

3. As a generality, the researcher should make sure that the research questions being asked are focussed and the study case criteria used are well defined to avoid unnecessary 'fishing' or being overloaded with excessive volumes of undifferentiated and irrelevant data; particularly as there is also an increased risk of inadvertent personal data disclosure.

Legal background to clinical record ownership and use of personal data

4. Data are only personal data when they identify and relate to a living person. The use and 'processing' of all identifying personal data are regulated under the Data Protection Act (2018) in the UK (GDPR 2018 in the EU) and vets have obligations, duties and responsibilities that flow from this legislation (https://ico.org.uk). Often such obligations and controls are under the auspices of a designated Data Controller or a Data Protection Officer in the applicant's host practice. Normally data retrieval is by diagnosis rather than by animal / owner name (although the latter may occasionally be useful for genetic screening of breed lines), and some areas of study may potentially involve processing personal data e.g. evaluating owner behaviour, or owner treatment choices.

5. While a veterinary practice may 'own' the clinical records, such information is privileged because it will inevitably include personal data (data that would identify the person involved) (https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/clinical-and-client-records/ §13.12). NB. Personal data will often also be referenced in accompanying clinical findings, such as radiographic images, laboratory reports, PM findings, etc.

Access and use of clinical records data – consent issues

6. Participating practices may be asked to provide consent for the use of their clinical data records for a research project, possibly as part of a multicentre study, and they will need an Information Sheet about the study before deciding whether to allow access to those records.
7. Participation in a research study could also involve contacting one of the practice clients directly e.g. by email, phone, letter and in which case clients must have given specific consent for this to be done, otherwise, all contact must be made by the veterinarian at the practice with responsibility for the case.

8. It can be argued that the owner/client has a moral interest in the use of clinical (non-personal data) records of their animal and should also consent to any use of that data. Ideally, consent from the animal owner/keeper to use clinical data would have been obtained prior to the research project taking place (https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/use-and-re-use-of-samples-images-post-mortems-and-disposal/§12.9). Notwithstanding client consent, clinical records covering a specific clinical research project may still be made available by the practice using

anonymisation or *pseudonymisation* (see §15 to 17 below) to ensure that no personal data are ever transferred. (https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/clinical-and-client-records/ §13.13).

9. Obtaining informed consent for the use of clinical data for research at the time of client enrolment is obviously the most convenient approach and it is recommended that this should be standard practice. The second most convenient way is to obtain consent at the beginning of a course of treatment. Owner informed consent should include the transfer of un-anonymised clinical data to allow for referral to another practice or institution, as well as for anonymised records to facilitate participation in a research study.

10. Importantly, it should be noted that contacting owners involves additional ethical problems e.g. if an owner has recently lost an animal or does not want to be reminded about a pet that has died or had to be euthanised, as they may become quite distressed by such contact (even though they had previously consented to be contacted). Great sensitivity and awareness always need to be shown by the researcher on contacting owners, and asking questions during an interview. Initial contact with owners should always allow for the owner to choose whether to be involved, and how and when to be contacted. A non-response to a reminder should normally be treated as an unwillingness to be involved.

Integrity of clinical record data (e.g. reliability, completeness)

11. Poor data and its analysis will jeopardise the future welfare of animals receiving any recommended treatment (or the converse may be true if a beneficial treatment is inaccurately classified) and is an important and critical factor in an ethics analysis.

12. While clinical records provide a potentially rich source of information the data have to be retrieved, selected, collated, and analysed with scientific rigour. If more than one clinical centre is involved the researcher should be aware of the different standards of record keeping, and that some records may be less relevant because the type of treatment has advanced. Furthermore, in the treatment of some diseases, the records of referral practices and first opinion practices can be quite different and so it helps if the context and details of the criteria used for the study are clearly laid out (see §3).

13. Data taken from clinical records can often be strengthened by the addition of missing data points (e.g., retrospective quality of life issues, survival outcomes) and retrieving such data may involve going back to the practice and the veterinary surgeons involved, or even contacting the owner (see §10). If records are several years old obtaining a useful dataset may be frustrated by the lack of consent for its use by the owner, by the memories of both veterinary surgeons and owners, and that all may be subject to various biases.

14. Another limitation on the use of clinical data includes an insufficient number of cases which is important for statistical confidence. Using a multicentre approach to gather sufficient data will often lead to better quality publications (see RCVS https://www.rcvs.org.uk/document-library/rcvs-ethics-review-panel-erp-guidance-on-multicentre-studies-in/) (see §12)

Some notes on data transfer, anonymisation, storage and destruction

15. Full anonymisation of clinical records, where all traceable elements to owners' personal data have been removed is the safest. In practice this can be achieved in two ways. The practice could provide clinical data only, having removed any traceable links in a spreadsheet record or in a redacted clinical record. Or secondly, transfer using partial anonymisation (pseudonymisation) where a linkage step is made between the clinical record and the transmitted clinical record, is the commonest, easiest and most practical way to transfer data. Moreover, it allows for a limited follow-up by authorised persons in the practice through the link (therefore it is not full anonymisation). In this way the owner/originator of the clinical record has control of the personal data as they hold the linkage key (e.g. Case 1123 = Fluffy Smith). Pseudonymisation and clinical data transfer does not require consent from the client providing no personal data are ever revealed (see §8).

16. It is a practice requirement that all clinical data is kept in a safe data storage system, and is run by adequately trained staff. When pseudonymised clinical data are transferred a date for destruction of the personal data link is required. NB. There is no time limit for keeping anonymised clinical data (e.g., pseudonymised clinical data after the link has been destroyed) and it may even be required by some research sponsors and journals to allow for future re-analysis.

17. The provision of third party access to a clinical record must be approached with caution as certain types of data, even if not directly personal, can reveal the identity of an individual via triangulation. For example: knowing the geographic area or postcode, together with knowing the type and breed of animal could allow an informed guess as to the person(s) involved.