UK Kidney Association

Legal & ethical permissions required to process UKRR data

The UKRR has to ensure that all external researchers or clinicians requesting UKRR data have the necessary permissions and approvals in place prior to receiving UKRR data. This document details what these permissions are and the evidence you must submit alongside your data application and data protection and impact assessment (DPIA).

Audit/service evaluation or research?

Defining the purpose for which you want to use UKRR data is key, because this determines what permissions you need to have in place to receive the data. The UKRR shares data for two purposes:

(i) **Audit/service evaluation** – audit and service evaluation projects seek, respectively, to measure clinical practice against published guidelines and evaluate the quality of the service provided. These projects may be comparative, but they do not seek to establish generalisable conclusions, e.g. ILD18 and ILD79 – see projects.

(ii) **Research** – research projects aim to generate new knowledge that can be generalised. Most projects approved to use UKRR data fall into this category – see projects.

Two resources to help you categorise your project are:

- Twycross & Shorten's paper: 'Service evaluation, audit and research: what is the difference?'
- The Health Research Authority's (HRA) website.

If you believe your project is audit, you must complete the HRA's audit and research tool and submit the output alongside your data application and DPIA. You will not need to provide evidence for research ethics, so can skip to the section 'Common law duty of confidentiality'.

Research ethics

The UK Kidney Association (UKKA) holds research ethics permissions for the UKRR (ref: 21/NE/0045) to populate and maintain a research database for the purposes of providing high quality data for studies and clinical trials.

Applicants applying to the UKRR for data for research purposes must be able to either:

(i) Provide evidence that their research project has been granted research ethics permissions by a national or local research ethics committee or

(ii) Provide evidence that their research project does not require research ethics approval. This can be determined using the HRA's ethics tool.

Applicants should be aware that their institutions may have specific rules regarding what kinds of study require ethical approval and all applicants should consult their institutions' policies.

Common law duty of confidentiality

All projects that use patient data, whether research or not, must be able to provide evidence that they have satisfied the common law duty of confidentiality. This duty states that beyond its use for the direct care or treatment of patients, permission must be given for all use of a patient's confidential information.

Permission can be granted in two forms:

(i) **Consent** – patients can voluntarily consent for their data to be included in purposes beyond their direct care e.g. audit and research. For consent to be valid the patient must have been informed of how the data will be used and why, have given a positive and unambiguous statement confirming their consent (ideally in writing) and have the right to withdraw at any time. Projects that rely on patient consent to receive and process confidential information, e.g. clinical trials, must provide a copy of the patient information sheet and the template consent form.

(ii) **Secondary use permissions under s251 of the NHS Act (2006) –** where it is not possible or feasible to collect patient consent for a project, applicants may use permissions granted under s251 of the NHS Act (2006) (s251 permissions) to collect patient data. s251 permissions are granted by the HRA's Confidentiality Advisory Group (HRA CAG) – see their guidance. The scenarios below give specific details:

- Clinicians conducting audit/service evaluation studies based only on previously collected UKRR data and who do not want to contact patients, can receive UKRR data under the UKKA's audit s251 permissions (ref: 16/CAG/0153)
- Researchers conducting studies based only on previously collected UKRR data, and who neither want to link to another dataset nor to contact patients, will be able to receive UKRR data under the UKKA's research s251 permissions (ref: 16/CAG/0064)
- Researchers conducting studies based only on previously collected UKRR data, but who want to link to another dataset and/or who intend to contact patients, must apply for and be granted s251 permissions for their projects.

Summary of evidence that must accompany your data application and DPIA

Evidence	Audit/service evaluation	Research
Output of HRA audit/research tool	✓	×
REC approval or output of HRA ethics tool	×	✓
Patient information sheet and consent form	×	If participation consented
s251 approval letter/ref number	×	If participation unconsented and your own s251 is required – see scenarios above