**Rare Disease Group (RDG) Lead Contract**

This contract forms the agreement between the Rare Disease Group (RDG) Lead and the Rare Disease Committee (RDC) on behalf of the UK Kidney Association (Legally known as the Renal Association).

**1. Approval**

To be approved by the UK Kidney Association (UKKA), the RDG Lead must ensure they and the RDG comply with the requirements set out below. Approval is essential for the RDG to use RaDaR, the rare disease registry. The RDC can suspend access to RaDaR if the group does not abide by its contractual requirements.

**2. Requirements of the RDG Lead**

The RDG Lead should be a UK based Nephrologist.

The RDG lead is expected to:

1. Have a signed and approved RDG application form.
2. Attend the 1-day annual RDG Lead meeting.
3. Provide and maintain information for clinicians and patients/carers to be published on rarerenal.org.
4. Maintain an up-to-date RDG membership list to appear on rarerenal.org.
5. Submit an annual report to the RaDaR Operational Management Group the by the 31st of March each year.
6. Communicate with the RaDaR Operational Management Group in a timely manner (considered to be 10 days for email responses).
7. Review the content of the RDG application form every 3 years.
8. Succession plan.

The RDG may delegate some of his/her duties but retains responsibility for them.

The term of office for an RDG Lead is 3 years. This may be extended at the discretion of the RDC.

**3. Requirements of an RDG**

The RDG is expected to:

1. Openly recruit group members so that the RDG fairly represents national expertise for the condition. This should include at least one trainee, nurse, clinical and non-clinical expert. The RDG Lead should attempt to recruit members from all devolved nations and all applicable disciplines. If the RaDaR Team do not feel there is sufficient representation, an advert will be sent out on behalf of the RDG inviting expressions of interest from the UKKA membership.
2. Include at least one patient representative.
3. Meet as a group at least once per year.
4. Communicate with Nephrologists to encourage UK-wide recruitment.
5. Provide a definition of the diagnostic characteristics that pertain to the patient group, with clear inclusion and exclusion criteria, and ICD or SNOMED codes if applicable. This information is necessary to enable electronic transfer of data into the database and international collaboration.
	1. Inform the RaDaR Operational Management Group of any outputs/publications/conference submissions and to ensure these include the appropriate acknowledgements.
	2. Have sufficient administrative support for the smooth running of the RDG.
	3. Provide support for research projects.

**4. Use of RaDaR**

Approved RDG leads and their associated colleagues may use RaDaR for the following purposes:

1. To develop and maintain a secure patient registry capable of holding detailed longitudinal clinical data specific for that condition.
2. To collect research specific data pseudonymously linked to patients.
3. To contact patients in accordance with Research Ethical Committee approval.
4. To receive reports from the RaDaR Operational Management Group regarding renal unit recruitment and governance issues.

**5. RaDaR Operational Management Group responsibilities to the RDG**

1. The RaDaR Operational Management Group, through its contract with UK Renal Registry (UKRR) and compliance with the UKKA information governance policies, procedures and approvals will be responsible for the security and maintenance of RaDaR and rarerenal.org.
2. The RaDaR Operational Management Group will audit the registry data from time to time.
3. The UKRR will maintain the RaDaR data indefinitely, in accordance with the database governance and approvals. This means that if an RDG disbands or is inactive temporarily the data will remain available.
4. Anonymised and encrypted data may be exported to external research organisations, with appropriate ethics approval and patient consent, at the request of a RDG and with any data sharing agreement being approved by the RaDaR Data Access Group. Data will only be exported if approved by the RDG Lead.

**6. Patient Recruitment and Consent**

There are two levels of consent, generic and specific*,* (paper and electronic) which in practice can be obtained together. The RaDaR Operational Management Group contracts to the UKKA for all governance issues relating to RaDaR. The UKKA is responsible for Research Ethical Committee approval of generic consent for patients to participate in RaDaR. This has been obtained from the South West - Central Bristol REC, reference 14/SW/1088. The generic consent documents can be accessed on rarerenal.org and all RDGs must be aware of and abide by these documents. Failure to do so may result in the removal of access to RaDaR.

The RDG will be responsible for the specific consent that is needed for every additional research activity involving patients in RaDaR. Copies of such approvals need to be sent to the RaDaR Operational Management Group so appropriate governance can be arranged.

Generic Consent

1. This consent allows collection of patient data into RaDaR, and pseudonymised contact between the RDG and the patient via the local investigator. By agreeing to participate in RaDaR, patients give permission to be approached by the RDG, via their clinician, regarding patient days, possible further research studies etc. Generic consent does not permit additional research activity.
2. The local investigator in each participating renal unit is responsible for obtaining consent. He or she will be recognised by the UKKA as a participating clinician approved to enter patients. Access to RaDaR will be provided by the RaDaR Operational Management Group or a member of the UKKA data team. All nephrologists and paediatric nephrologists with a licence to practise in the UK can be given a login to enter and view data. Access will also be provided to local research nurses or research fellows, identified to collect data by the local investigator.
3. Patients will be approached by the local investigator or a member of their team*.* Patients will be required to give written consent to participate in RaDaR, using the age-appropriate consent or assent forms available on rarerenal.org. Copies of the consent documents must be filed in the patient's medical record and the RaDaR site file and the patient should be given a copy for themselves.

Specific Consent

1. Patients who participate in RaDaR may be invited to take part in further research projects proposed by a RDG and covered by specific consent. The RDG is responsible for obtaining and maintaining separate Research Ethics Committee agreement for all specific research activity. The RDG must notify the RaDaR Operational Management Group of the terms and dates of REC approvals and provide a copy of the research protocol.
2. The local investigators will be responsible for recruitment at their sites. They will also be responsible for abiding by the specific requirements of each study in terms of consent procedures, completion of the minimum dataset and follow up data as required, and sample collection if applicable. Details of specific research studies may be included on rarerenal.org but their organisation is the responsibility of the RDG and not the RaDaR Operational Management Group or the RDC.
3. RDGs may use RaDaR to collect study-specific data, subject to ethics approval and with permission from the RaDaR Operational Management Group.

**7. Finances**

1. The Rare Disease Committee, with the support of the UKKA, is responsible for the financial sustainability of RaDaR.
2. RDGs must be self-supporting and may obtain their funding from various sources. These may include research grants, NHS service charges, and charitable contributions by organisations promoting improved welfare of individuals with a specific disease, as well as grants from the pharmaceutical industry.

**8. Data analysis**

1. The process for conducting non-commercially supported research using data held by RaDaR is set out at <https://ukkidney.org/audit-research/how-access-data/radar-data/apply-access-radar-data-analyses> .
2. Research using RaDaR data on behalf of (or funded by) any commercial organisation will only be carried out following execution of a legal agreement between the UKKA and the commercial organisation(s) concerned.

**9. Signatures**

Confirmation of acceptance of this agreement.

Name of Lead

Signature of RDG Lead

Date

Name of RaDaR Director

Signature of RaDaR Director

Date

This contract should be renewed every 3 years from date of signing.

RaDaR Operational Management Group email: radar@ukkidney.org