National Joint Registry
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Working for patients, driving forward quality

NJR guidance for research study applications

NJR Supported Project (External)

- An NJR supported project will request **aggregate** or **summary data only**, or **pseudonymised or anonymised patient level data.**
- These projects are external to, but supported by, the NJR. Requests requiring access to patient, surgeon, or unit personal identifiers, or implant batch number **will not be granted.** NJR will not provide personal identifiers or NJR linked datasets for external projects.
- Investigators who are considering including NJR data in external funding applications are required to receive approval in principle for their project application **before** it is submitted to the grant body for funding request. The NJR research office can provide confidential advice on protocols and letters of support where appropriate.

NJR Partnership Project (Internal or collaborative)

- An NJR partnership project is a study that requests **sensitive and/or identifiable data** (requested through approval by the Confidentiality Advisory Group (CAG) of the Health Research Authority), or **data linked to external datasets,** such as PROMS, HES, or ONS (requested through NHS Digital), CPRD (accessed through the MHRA) or PEDW (accessed through NHS Wales Informatics Service).
- These projects are undertaken **in partnership with the NJR** and require an identified named collaborator from the NJR Steering Committee or NJR Research Committee.
- NJR Partnership Projects require Principal Investigator attendance at a Research Committee meeting before an application can be approved.
- All NJR Partnership Projects requesting patient, surgeon, or unit personal identifiers, product batch number, or linkage to external datasets are reviewed in the context of our existing project activity.
- In general, proposed work that might duplicate or overlap with existing research will only be considered if the added value of carrying out the work is justified clearly.
- Applicants wishing to pursue NJR Partnership projects - those requiring any linked data from NHS Digital, those requiring access to patient identifiers through the Confidentiality Advisory Group of the Health Research Authority, or prospective studies requiring National Research Ethics Service ethics committee approval – may wish to submit parallel applications to these bodies alongside RC application. Applicants should discuss their required permissions with the NJR prior to any external submissions. An approved EOI must be in place before any such submissions are made.
- All applications involving use of linked NJR data or personal identifiers, or ethics committee approval must be channelled through the NJR application process in the first instance. Upon receipt of RC and data controller approval, the applicant will be required to provide all approvals prior to data release. All submissions to NHSD, CAG, NRES, or other body must be made in collaboration with the agreed internal NJR steering committee collaborator.

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General guidance

- Applications will only be approved for projects with well-defined aims, objectives, protocol, and timeline. Open ended access to NJR data will not be made available and extensions beyond the standard 12 month project duration require formal approval at the discretion of the Research Sub-committee.
- Applicants will not have exclusive access to the data.
- Applicants, and their hosting institutions, must agree to adhere to the terms and conditions of the data release, without exception, before any release of data will be considered.
- Data access will normally incur a charge, depending on the scope, nature and scale of the proposed project.
- Disseminating information on current research, presentations and publications is a priority for the NJR. Applicants, in receipt of NJR data for research, will be expected to provide regular reports and conform to the NJR's publication policy. In all such work, the NJR expects to be acknowledged appropriately, please refer to the NJR research request website page for the guidelines for **acknowledgment of the NJR.**
- Once an approved project is underway, any extension beyond the agreed project scope/identified study remit must be sought via written permission from the NJR Research Sub-committee.
- We recommend all projects seek dedicated statistical support to inform the study design and require the statistician responsible to co-sign the research application form.
- All approved research studies are required to submit a 6 month interim progress report, and final report to the NJR, using the template available on the website.
- It is a requirement that the research study PI must be in a substantive contract post i.e. not working under a fixed- term or temporary contract.
- Finally, please note that authentic e-signatures are admissible but digital signatures will only be accepted if they are image files i.e. names typed as a placeholder cannot be accepted.