

**MSBase Foundation Ltd**

Central Clinical School
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Dear MSBase Registry Principal Investigator

Please inform your NHS Organisation's Research and Development (R&D) Department about your decision to participate in MSBase Registry. You may wish to forward on this document along with the MSBase Protocol document and REC FO for R&D records.

Please note the following points:

- The MSBase Registry (which is established/hosted in Australia) falls outside the scope of the UK Policy Framework for Health and Social Care Research.
- Research permission/confirmation of C&C is not required by collaborators at data collection centres (DCCs) who provide data under the terms of a supply agreement between the organisation and the registry/database i.e. MSBase Foundation Ltd. DCCs are not research sites.
- There is no formal requirement for registries/databases to apply for ethical review under NHS research governance systems. Ethical approval would only be required by legislation if processing identifiable data without consent. Applications for ethical review can however be made on a voluntary basis. However, because the MSBase Registry is hosted/established outside of the UK (in Australia), under "*Standard Operating Procedures for Research Ethics Committees*" it is not eligible for voluntary REC review as a registry/database in the UK.
- In order to assure the processes for recruitment of participants via the NHS, following advice from the HRA, MSBase Foundation Ltd. has sought review for elements of the registry by a UK REC, completing an IRAS application for a "*Study limited to working with data (specific project only)*" on the advice of the HRA.
- The REC favourable opinion received from *Yorkshire & The Humber - South Yorkshire Research Ethics Committee* applies only to the participant recruitment procedures. The REC review does not extend to the establishment and management of the database/registry in Australia.

- Sub-studies/research run from the registry using data which is anonymous to the researchers and where the person from whom the data originated cannot be identified (alone or in combination with other linked data) are exempt from NHS or HSC REC review.
- Any other sub-studies/research using data supplied by the registry/database must apply for ethical opinion and to R&D offices at all organisations where the research is conducted.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Orla Gray'.

Dr Orla Gray

Consultant Neurologist/U.K. Chief Investigator