



Health Research Authority

London - Queen Square Research Ethics Committee

HRA NRES Centre Bristol
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29 September 2021

Professor John Dark
Professor of Cardiothoracic Surgery
Newcastle University
Faculty of Medical Sciences
Framlington Place
Newcastle Upon Tyne
NE2 4HH

Dear Professor Dark,

Study title:	Statins in Organ Donor Management An evaluation of the benefits of a single dose of Simvastatin given to potential organ donors declared dead by neurological criteria on outcomes in organ recipients
REC reference:	21/LO/0412
Protocol number:	9691
IRAS project ID:	288722

Regarding the above study, the HRA's position is that there is no requirement for GCP formal training and the research should be conducted in such a way that respect the rights, safety and wellbeing of research participants as per our website at <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/joint-statement-application-good-clinical-practice-training-researchers-hra-mhra-de-volved-administrations-northern-ireland-scotland-and-wales/>.

The need for GCP should be determined by the sponsor, in its risk assessment, as it considers how it will ensure the above. This should be determined by the activities being undertaken by individual researchers and whether these activities fall outside of what would be considered their usual care competence. If it is within their normal duties and their usual care competence, then there is no requirement for GCP or Research CVs.

Yours sincerely

Kevin Ahmed
Approvals Manager