

## Delegation by NHS [insert name] CCG to NHS Nottingham City CCG to exercise functions relating to Excess Treatment Costs arising from Non Commercial Interventional Research

- A. The functions set out below in paragraph B are hereby delegated by NHS [insert name of delegating CCG] ('the CCG') to NHS Nottingham City CCG ('the Lead CCG') in accordance with its statutory powers under s.14Z3 of the NHS Act 2006 (as amended) ('the Act'). s.14Z3 of the Act allows CCGs to make arrangements in respect of the exercise of their functions and includes the ability for one CCG to exercise the functions delegated to it by another CCG or CCGs (see Schedule 1 for a list of delegating CCGs).
- B. The functions which are being delegated relate to *The new excess treatment costs ('ETCs') management model* for CCGs ('the Programme') which has been designed to deliver a national standardised process for managing and reimbursing excess treatment costs in the services provided by the providers. The providers include multiple NHS Trusts, FTs, GP Practices and non-NHS providers (contracted to provide NHS services) across the country which carry out non-commercial research in the NHS. As part of this work it is necessary to consider interdependencies between these services and any other services that are affected. The functions which are delegated relate to the management of excess treatment costs arising from the delivery of non-commercial clinical research in the NHS.

Excess treatment costs are the difference between the total NHS treatment costs and the cost of standard treatment in a non-commercial research study (where the difference is greater than the cost of standard care). ETCs are part of NHS treatment costs which are funded by the NHS through normal commissioning arrangements for patient care.

The expectation is that the CCG will ensure that clear governance arrangements are put in place so that they can assure themselves that the exercise by the Lead CCG of their functions is compliant with statute

Under the arrangements of the new ETC management model, a national ETC budget for CCGs will be formed via a deduction to each CCG's annual allocation by NHS England and transferred to the Department of Health and Social Care (DHSC) to be managed by National Institute for Health Research (NIHR) Local Clinical Research Network ('LCRN') (see section D). Each CCGs defined annual allocation will be determined in agreement with NHS Clinical Commissioners (NHSCC) and NHS England's Finance Working Group.

- C. The Lead CCG shall also have regard to the following functions so that it can achieve the purpose set out in (A) above:

- a. Acting with a view to securing continuous improvement to the quality of commissioned services in so far as these services are included within the scope of the Programme. This will include outcomes for patients with regard to clinical effectiveness, safety and patient experience to contribute to improved patient outcomes across the NHS Outcomes Framework
- b. Promoting innovation in so far as this affects the services included within the scope of the Project/Programme, seeking out and adopting best practice, by supporting research and adopting and diffusing transformative, innovative ideas, products, services and clinical practice within its commissioned services, which add value in relation to quality and productivity.
- c. The requirement to comply with the statutory duty under s.149 of the Equality Act 2010 i.e. the public sector equality duty.
- d. The requirement to have regard to the other statutory obligations set out in section 14 of the Act. The following are relevant but this is not an exhaustive list:
  - 14P - Duty to promote the NHS Constitution
  - 14Q - Duty to exercise functions effectively, efficiently and economically
  - 14R – Duty as to improvement in quality of services
  - 14T - Duty as to reducing inequalities
  - 14U – Duty to promote involvement of each patient
  - 14V - Duty as to patient choice
  - 14W – Duty to obtain appropriate advice
  - 14X – Duty to promote innovation
  - 14Y – Duty in respect of research
  - 14Z - Duty as to promoting education and training
  - 14Z1- Duty as to promoting integration
  - 14Z2 - Public involvement and consultation by NHS England/CCGs
  
  - 14O – Registers of Interests and management of conflicts of interest
  - 14S – Duty in relation to quality of primary medical services
- f. The Lead CCG will also have regard to the financial duties imposed on CCGs under the NHS Act 2006s, taking into account that the budget for ETCs will be top-sliced from each CCG and go direct to the DHSC, as set out in:
  - 223G – Means of meeting expenditure of CCGs out of public funds
  - 223H – Financial duties of CCGs: expenditure
  - 223I - Financial duties of CCGs: use of resources
  - 223J - Financial duties of CCGs: additional controls of resource use
- g. Further, the Lead CCG must have regard to the Information Standards as set out in ss.250, 251, 251A, 251B and 251C of the Health & Social Care Act 2012 (as amended) and under the General Data Protection Regulation and Data Protection Act 2018.

- D.** The role of the Lead CCG shall be to carry out the functions relating to decision making on pertinent ETCs commissioning issues that arise from the Programme. The Lead CCG can exercise this function through any of the mechanisms allowed under the Act and its constitution. This includes, but is not limited to, the following activities:
- a. The Lead CCG shall undertake the commissioning function for ETCs on behalf of the CCG and other CCGs, see Schedule 1, within the National Institute for Health Research (**NIHR**) Local Clinical Research Network ('**LCRN**') region
  - b. The Lead CCG shall enter into agreement with NIHR LCRN that ETCs will be managed by NIHR LCRN under the ETC commissioning policy. The Lead CCG, who shall be able to nominate a lead individual within its organisation to make decisions on ETCs under this delegation, will be called upon for any decisions regarding ETCs requests or resolution of any matters that fall outside the commissioning policy.
  - c. Such other issues as arise and fall within the parameters of this delegation relating to ETCs arising from Non Commercial Interventional Research.
- E.** At all times, the Lead CCG, through undertaking the decision making function of the CCG will act in accordance with the terms of their constitution. No decision outcome shall impede any organisation in the fulfilment of its statutory duties.
- F.** *This delegation shall be reviewed every year by the CCG before 31 March. If the delegation is not to be renewed then the CCG will give the Lead CCG a minimum of six months' notice and the delegation will end on the next 31 March following the expiration of that six month notice period.*

Signed on behalf of the delegating CCG:

Name:

Role:

Signature:

Date:

Signed on behalf of the lead CCG:

Name:

Role:

Signature:

Date:

**Schedule 1** List of delegating CCGs

NHS Lincolnshire East CCG  
NHS Corby CCG  
NHS East Leicestershire and Rutland CCG  
NHS Erewash CCG  
NHS Hardwick CCG  
NHS Leicester City CCG  
NHS Lincolnshire West CCG  
NHS Mansfield and Ashfield CCG  
NHS Nene CCG  
NHS Newark and Sherwood CCG  
NHS North Derbyshire CCG  
NHS Nottingham North and East CCG  
NHS Nottingham West CCG  
NHS Rushcliffe CCG  
NHS South West Lincolnshire CCG  
NHS Southern Derbyshire CCG  
NHS West Leicestershire CCG  
NHS South Lincolnshire CCG

Schedule 1