How Excess Treatment Costs will be covered for existing studies* in England after 1 October 2018

The existing study involves healthcare services mostly commissioned by...

- Clinical Commissioning Groups
- Specialised Commissioning or Public Health England

- The single per patient ETC value for the study and patient recruitment activity, as defined by the CRN and reported after 1 October 2018 in the NIHR Central Portfolio Management system will contribute towards threshold, calculate payments due after reaching threshold, paid through Local CRN, enable delivery through existing research process

Study has only one per patient ETC value agreed or calculated

- ETC value provided to NHSE via CCG data collection to enable payment calculation

Study has multiple ETC values agreed with different CCGs or calculated by different sites

- ETC value not yet provided

**ETC VALUE WILL BE CALCULATED ON BEHALF OF STUDY**

Using existing Schedule of Events from HRA submission content to apply to cost attribution tool methodology OR IF UNAVAILABLE Sponsors will be contacted directly

Secondary Care Trust - Organisation-wide threshold for collective ETC values of research portfolio to be met by Trust BEFORE payments received - set at 0.01% of 16/17 published operating income or £10,000 for provider - contact your Local CRN for further details

All study sites to receive the single ETC value for the study for all patient recruitment activity after 1 October 2018

- Primary Care Provider - NO threshold applied. Payments received after minimum invoice value of £100 is reached

Existing arrangements for ETC remain in place. Existing specialist commissioning studies (defined as specialised commissioning studies awarded research funding before 1 October 2018) do NOT enter new system

*Excludes studies resulting from new single stage or final stage funding calls after 1 October 2018
## Worked Examples - CCG services study

### Single arm study

- Trust A has an organisation-wide threshold of £10,000
- This study's predicted requirement is 24 patients per year
- An ETC value of £2,000 has already been agreed with a CCG and reported to NHSE via the data request ahead of the 1 October
- Given the £2,000 per patient ETC value, 5 patients would need to be recruited in the year by Trust A to reach the threshold
- The 6th patient recruited by Trust A would trigger payment of £2,000 for ETCs
- ETC payments could be triggered earlier if Trust A participates in additional studies with ETCs as recruitment to these studies also contribute towards reaching Trust A’s threshold
- The more studies with ETCs that are participated and recruited to, the sooner the threshold can be reached and payments triggered

### Multi arm study

- Trust B has an organisation-wide threshold of £10,000
- This study's predicted requirement is 24 patients per year: 12 receiving the excess treatment and 12 receiving standard treatment
- An ETC value of £2,000 has already been agreed with a CCG and reported to NHSE via the data request ahead of the 1 October
- To accommodate randomisation, the £2,000 ETC value is converted to an average per patient ETC value of £1,000
- 10 patients would need to be recruited in the year by Trust B to reach the threshold
- The 11th patient recruited by Trust B would trigger payment of £1,000 for ETCs
- ETC payments could be triggered earlier if Trust B participates in additional studies with ETCs as recruitment to these studies also contribute towards reaching Trust B’s threshold
- The more studies with ETCs that are participated and recruited to, the sooner the threshold can be reached and payments triggered

### Key points to note

- The ETC is a single value for the study meaning all NHS Providers receive the same payment and ensures all ETC activities are covered regardless of variation in standard of care or if patients are randomised to different treatment arms
- As a result, some NHS providers may generate a level of cost saving while others will remain cost neutral - this will vary on a study by study basis throughout the year
- There is no change required to clinical coding or financial reporting of commissioned activities
- There is no application process for NHS providers participating in studies, the payments will be triggered through existing research activities (recruitment upload to the NIHR Central Portfolio Management System) and made via the existing Local CRN infrastructure
- Any appeals against the ETC value utilises will only be considered where submitted by the Sponsor to supportmystudy@nihr.ac.uk along with supporting evidence from the funding application