**Excess Treatment and Service Support Cost Application Form**

**For Secondary Care**

This form should be used to:

* apply for Excess Treatment Costs (ETCs) for a site in Northern Ireland where no approved SoECAT is available e.g. where the funder is based outside the UK and no SoECAT has been requested ***Please note: a SoECAT may be requested for the study***
* apply for NI site ETCs for a study where an approved SoECAT is available*, but a different ETC value is requested* due to e.g. significant differences in Standard of Care costs
* Apply for Service Support Costs where a study is taking place at a site in Northern Ireland, **and** is not supported by NICRN or NICTN **and** SSC activities represent a real cost to a care delivery organisation **and** no other source of funding is available.

Please include the following with your submission:

* Approved SoECAT, Schedule of Events and/or any available evidence of approval of ETCs in other UK jurisdictions
* Grant Award letter or Site Agreement/draft CTA if available
* IRAS application
* Study Protocol

|  |  |
| --- | --- |
| **Study acronym** |  |
| **ETC Funding Amount requested** | £ |
| **SSC Funding Amount requested** | £ |
| **NI Site Name (Trust)** |  |
| **Details of Study Contact at Site:** |
| **Name**  |  |
| **Email** |  |
| **Telephone** |  |

Please send a scanned signed copy to:

[researchsupport@hscni.net](researchsupport%40hscni.net%20) and [Sorcha.finnegan@hscni.net](Sorcha.finnegan%40hscni.net)

Or complete and forward to:

Research Support

HSC R&D Division

9th Floor, Linum Chambers

Bedford Street, Belfast, BT2 7ES

**Section 1 - Study Information**

|  |
| --- |
| **Full study name** |
|  |
| **Sponsor** |
|  |
| **Edge/CPMS portfolio number or IRAS reference number** |
|  |
| **Grant funder** |
|  |
| **Grant award date if known** |
|  |
| **Total grant award (e.g. from IRAS form)** |
| £ |
|  |
| **Please give details of where the study will take place in Northern Ireland (setting) – this should include details of where participants will be recruited, where an intervention will be delivered, and where any follow-up will take place.**Please note that the site type and activities carried out at different site types will affect the ETC value.It is vital that the Sponsor and/or CI/PI have considered the different site type(s) and associated activities. Within a study there may be more than one site type, with different activities at different sites. If this is the case for your study it is expected that you have access to a soECAT that accurately reflects the activities that are taking place at your NI site. This may result in more than one soECAT for a study and these would have formed part of the IRAS submission. If this is the case please complete a separate ETC application form for each different site type that you wish to claim ETCs for. Please also attach the relevant soECAT (you may need to contact the CI to access this document). If you require further information or clarification please contact the HSC R&D Division. |
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**Section 2 - Study Team Information**

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| **Chief Investigator** |
| Title: |  | Address: |
| Name: |  |  |
| Employing organisation: |  |
| Job Title/Post: |  |
| E-mail: |  |
| Telephone: |  |

|  |
| --- |
| **Principal Investigator at Northern Ireland site**  |
| Title: |  | Address: |
| Name: |  |  |
| Employing organisation: |  |
| Job Title/Post: |  |
| E-mail: |  |
| Telephone: |  |

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| **Nominated study contact for any queries regarding the application (Sponsor contact)** |
| Title: |  | Address |
| Name: |  |  |
| Employing organisation: |  |
| Job Title/Post: |  |
| E-mail: |  |
| Telephone: |  |

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| --- |
| **Trust R&D Office Contact(s)** |
| Name |  |
| Trust |  |
| E-mail |  |
| Telephone |  |

**Section 3 - Study Details**

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| **Overall start date of study** | **Overall end date of study** |
|  |  |
| **NI Site Recruitment Target** |  |
| **Study outline** (approx. 300 words) |  |
|  |
| **Proposed date from which ETCs will be incurred at the Northern Ireland site i.e. recruitment start date** | **Proposed end date when ETCs will cease to be incurred at the Northern Ireland site i.e. recruitment end date** |
|  |  |
| **Please enter the Per Participant ETC Value from SoECAT** | **£** |
| **Non-SoECAT ETC value requested (per participant – if different values are to be requested per arm, please provide details)** |
| £ |
| **If a SoECAT ETC value is available for the study, please provide an explanation as to why this is not being accepted at the NI site, and/or explain the differences in standard of care which result in additional ETCs over and above a SoECAT value. Information provided may be validated by a commissioner.** |
|  |
| **Anticipated recruitment schedule by financial year for the NI site** |
| **Financial Year (please amend as appropriate)** | **22/23** | **23/24** | **24/25** |
| Proposed number of Participants to be recruited |  |  |  |

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| **Proposed date from which SSCs will be incurred at the Northern Ireland site i.e. recruitment start date** | **Proposed end date when SSCs will cease to be incurred at the Northern Ireland site i.e. recruitment end date** |
|  |  |
| **Please enter SSC Value (per participant and approximate total)** | **£** |
| **Please provide a justification for this value** |  |

**In Sections 4 and 5, please provide information to justify the different ETC value that is being requested (if appropriate).**

**Section 4 Supporting Information: Standard of Care**

**Please provide details of the Standard of Care in Northern Ireland for participants in the study**

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| --- | --- |
| ***Total Standard of Care Cost (per participant)*** | ***£*** |
| ***Breakdown of Costs/Resources e.g. consultant time, nurse time, pharmacy time, imaging, drug acquisition cost etc.*** |
| ***Procedure/Activity*** | ***Undertaken by (if appropriate)*** | ***Cost*** |
| ***e.g. Scan*** | ***Radiographer*** | ***£300*** |
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| ***Total Cost*** | ***£*** |

**Section 5 – Supporting Information for Costs Requested**

**Please provide details of the excess treatment activities for Northern Ireland participants in the study. Please ensure your attributions are in-line with the AcoRD guidance, that the relevant HSCT R&D Department has been consulted and has signed the application form. If specific activities are not standard of care at Northern Ireland site, but have been considered standard of care in a SoECAT, please highlight them.**

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| ***Intervention Arm 1 ETCs (per participant)*** | ***£*** |
| ***Breakdown of Costs/Resources e.g. consultant time, nurse time, pharmacy time, imaging, drug acquisition cost etc.*** |
| ***Procedure/Activity*** | ***Undertaken by*** | ***Cost*** | ***Details e.g. number of timepoints*** |
| ***Arm 1*** | ***e.g. Additional blood sample*** | ***Clinic nurse*** | ***£20*** | ***Baseline, Month 1,2 and final visit*** |
|  | *e.g. Scan* | *Radiographer* | *£300* | *Baseline and final visit* |
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|  |  | **TOTAL COST** | e.g. £680 |  |

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| ***Intervention Arm 2 ETCs (per participant)*** | ***£*** |
| ***Breakdown of Costs/Resources e.g. consultant time, nurse time, pharmacy time, imaging, drug acquisition cost etc.*** |
| ***Procedure/Activity*** | ***Undertaken by*** | ***Cost*** | ***Details e.g. number of timepoints*** |
| ***Arm 2*** | ***e.g. Additional blood sample, imaging*** | ***Clinic nurse*** | ***£20*** |  |
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| ***Intervention Arm 3 ETCs (per participant)*** | ***£*** |
| ***Breakdown of Costs/Resources e.g. consultant time, nurse time, pharmacy time, imaging, drug acquisition cost etc.*** |
| ***Procedure/Activity*** | ***Undertaken by*** | ***Cost*** | ***Details e.g. number of timepoints*** |
| ***Arm 3*** | ***e.g. Additional blood sample, imaging*** | ***Clinic nurse*** | ***£20*** |  |
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| ***Intervention Arm 4 ETCs (per participant)*** | ***£*** |
| ***Breakdown of Costs/Resources e.g. consultant time, nurse time, pharmacy time, imaging, drug acquisition cost etc.*** |
| ***Procedure/Activity*** | ***Undertaken by*** | ***Cost*** | ***Details e.g. number of timepoints*** |
| ***Arm 4*** | ***e.g. Additional blood sample, imaging*** | ***Clinic nurse*** | ***£20*** |  |
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***Please add more columns and rows as needed***

**Section 6 – Summary of ETCs being requested**

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| --- | --- |
| **Standard of Care cost per participant (from Section 4)**  | **£** |
| **Financial Year** | **22/23** | **23/24** | **24/25** |
| Proposed number of Participants to be recruited |  |  |  |
| Total ETC value being request by financial year (ETC as detailed in Section 5 minus Standard of Care cost from Section 4) | £ | £ | £ |

**Section 7 - Declaration and Signatures**

I declare that the information given on the form is complete and correct.

I agree to update figures, and update the HSC R&D Division if any details are modified (e.g. number of sites or anticipated recruitment increases)

**Principal Investigator at NI Site**

Signature: Date:

Name:

**HSC R&D Finance Representative**

Signature: Date:

Name:

**HSC R&D Manager / Director**

Signature: Date:

Name:

Please send this form with the following documents electronically to researchsupport@hscni.net and Sorcha.finnegan@hscni.net

Funding provided from the HSC R&D Fund is subject to availability and may be affected by other pressures within the HSC; as a result, we are under no obligation to fund Excess Treatment Costs and Service Support Costs. Applicants may be required to seek funding for Excess Treatment Costs and Service Support Costs from other sources. We also reserve the right to refuse funding for any costs that are, in our view, inappropriate and/or excessive.