

Interactive Costing Tool (iCT)

Departmental, Set Up and Closedown Tariff 2020/21

Version 1.5 – 1st June 2020

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Section 1 - Description of document

Document content:

This tariff has been created to assist both Industry and NHS partners to create consistent and meaningful costings for Industry sponsored research within the NHS.

Values within this tariff do not include the relevant labour time required by research staff to initiate, carry out or report on the activity described.

All values include an indirect cost and capacity building and therefore only need the addition of the local PbR MFF from the Industry Costing Tool to produce valid figures.

All entries contain the following:

- **Grantplan or NIHR Coding** - Codes from the Industry Grantplan software or NIHR coding (for reference) where Grantplan coding is absent.
- **Activity Description** - Brief Description of activity taking place
- **Specialty** - Defined service support specialty that covers the activity (this may vary from one NHS organisation to another).
- **Notes** - Whether the activity is a single investigation, an intervention with associated investigation or a unit cost activity at setup or during the project.
- **2020/21 Costs** - The defined unitary cost for the activity including an indirect element

Please note that these are NHS costs only and do not represent costs provided by commercial or academic units. A degree of consideration will be required in order to cost any of these items in conjunction with external NHS SLAs contract to either of these entities.

The following tasks are deemed as part of the business service and are considered included in costs already in the costing template and therefore are NOT independently chargeable:

- *Set-up of any finance and IT information systems as required*
- *Invoice generation for all departments*
- *Any standard tasks performed by the Trust as part of normal or routine patient care*
- *Any trial related communications*

- Any standard administrative or management support and general maintenance of trial related paperwork (NOTE: this EXCLUDES data management)
- Pre-site selection or feasibility tasks
- Arrange/attend any introduction or qualification meetings
- Time research time spend preparing or attending inspections by regulatory bodies
- Time for any regulatory body inspections
- Medical record retrieval
- Internal contracts or paperwork for staff i.e. honorary contracts or University – Trust agreements for research staff
- PI duty of care responsibilities including Investigator review of safety reporting provided by COMPANY e.g. annual safety reports
- Storage space/co-ordination of equipment/notes
- Pre-screening (e.g. note searches) for non-stratified medicine/rare disease studies, however cost coverage for stratified medicine rare disease/study pre-screening resulting in significant workload for the participating organisation (e.g. data not recorded in routine patient notes) to be agreed on a study-by-study basis as required.
- Company audits (if necessary Company and Trust can negotiate a cost for a company requested audit with above-standard time requirements for staff involved)

Acknowledgements:

All costs in this document have been collated with the assistance of the following institutions and have been overseen and ratified by the Industry Costing Template Working Group, hosted by the NIHR CC.

- The Royal College of Pathologists
- Leeds Teaching Hospitals NHS Trust
- Royal College of Surgeons
- Bradford Ophthalmology Research Network
- University College London Hospitals NHS Foundation Trust
- Barts Health NHS Trust
- Queen Mary University of London
- Norfolk and Norwich NHS Foundation Trust
- NHS Health Education East of England
- National Pharmacy Clinical Trials Advisory Group
- The Shelford Group
- ECMC

- Sheffield Teaching Hospitals NHS Foundation Trust
- University Hospitals Bristol NHS Foundation Trust

Usage Disclaimer

All costs included herein are subject to change and amendment.

Recommendations for additions and amendments should be sent to phillip.good@nihr.ac.uk

Section 2 – Departmental, Setup and Closedown tariffs

Grantplan or NIHR Coding	Activity Description	Department	Notes	2020/21	Definition
NIHR_DEPT_001	General R&D fee	General Departments	Setup	£ 1,039	<p>Costing and model agreement negotiation across organisation for final agreement, including any sub-contracts/service level agreement/honorary contracts as required.</p> <p>Coordination of practical arrangements for confirmation of local capability and capacity across the organisation as required by HRA Approval. Further information is available in the CRN principles of good practice (link to be included to document). NOTE: Assessment is considered part of site selection and covered by the indirect and capacity building elements of the template.</p> <p>Research management activities, such as investigator file set-up and maintenance, including performance oversight for set-up and recruitment activities to deliver contracted requirements.</p> <p>Co-ordination of all close-down activities across the organisation to met Sponsor requirements.</p> <p>Provision of general support for Sponsor to understand organisation requirements in context of UK research environment.</p>

					<p>Local CRN team is available to provide support as required (link to contacts on website)</p> <p>Variations to value (increase or decrease) may occur in relation to study or therapy area complexity. The base calculated figure is based upon 30 hours setup time required by Managerial and administrative grade staff.</p>
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NIHR_DEPT_002	Archiving fee (per box) to be paid upon completion of study	General Departments	Closedown	£ 520	<p>Per box fee provided for paper archiving by research site for a minimum duration of at least 15 years unless stated otherwise stated. The study specific archive duration is defined by the Sponsor for that study type and where the Clinical Trials Regulation (CTR) EU No 536/2014 is applicable may be at least 25 years. Total charge is expected to be appropriately described in the model agreement financial appendix payment schedule to reflect volume/ required duration relevant for the study.</p> <p>Fee covers archiving preparation (including site archivist review where necessary), transfer, retrieval, access, indefinite storage and destruction (when instructed by Sponsor at end of agreed archive period) of site related trial material.</p> <p>Where site utilises an external third party archive, clarification of activities included in any quote should be provided to the Sponsor and the site's archiving preparation activities in such circumstances should be covered through the indirect/capacity building elements.</p> <p>Where the Sponsor takes responsibility for study archiving the fee should not be charged and the site's archiving preparation activities in such circumstances should be covered through the indirect/capacity building elements.</p>
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NIHR_DEPT_003	Chief Investigator fee	General Departments	Setup	£ 1,511	<p>The Chief Investigator has additional tasks covered by this fee which are associated with:</p> <ul style="list-style-type: none"> Ethics and MHRA review of documents Ethics submission Ethics meeting attendance Liaison with ethics assessment team Attendance at safety meetings throughout study Submission of Annual Progress Reports/ Development Safety Update Reports Provision of general medical oversight throughout the study including key teleconferences, Trial management, steering committee meetings to lead on study issues. Administration support time for activities listed above. <p>If Chief Investigator involvement is only signature of Ethics form, this fee is not chargeable</p> <p>Further activities, especially prior to site selection, should be considered as a separate consultancy service which is not covered in this fee. A separate consultancy contract/costing is recommended.</p>
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NIHR_DEPT_004	Clinical Research Facility set-up fee (only chargeable when specialist CRF is required for trial conduct or Sponsor has chosen to use facilities for potential study benefits)	General Departments	Setup	£ 1,456	<p>CRF is not part of standard patient care pathway and thus this resource space in Trusts must be paid for if required</p> <p>The fee is payable if:</p> <ul style="list-style-type: none"> -The Specialist CRF required for trial conduct -The company/Sponsor has chosen to use CRF due to potential recruitment benefit <p>No fee should be incurred by Company/Sponsor if Trust encounter capacity restraints and the use of the CRF is only option to retain the study or if there is minimal involvement e.g. room only use (this cost is covered by the indirect costs and should be distributed by the Trust to the CRF)</p> <p>The fees covers preliminary meetings with the CRF, study review, development, planning, set-up, delivery management and close down.</p>
NIHR_DEPT_005	Category A or B amendment fee (chargeable per amendment)	General Departments	In Flight	£ 297	<p>Only chargeable for category A or B amendments at that site requiring a change in documentation or process to conduct the study. Includes Review/implementation time by all relevant staff/departments for implementation, review and distribution.</p>
NIHR_DEPT_006	Training Fee (per hour per attending staff member) to be paid upon completion of training visits	General Departments	Setup	£ 78	
NIHR_DEPT_007	Monitoring Fee (per hour per attending staff member) to be paid quarterly in arrears	General Departments	In Flight	£ 78	

NIHR_DEPT_008	Set-up fee per Patient Inclusion Centre (PIC) used by site	General Departments	Setup	£	260	<p>Patient Identification Centre (PIC) payments, including hub and spoke models, for GP surgeries must be based on work performed with consideration for timeframes and can be capped using relevant wording in the financial arrangements in the contract.</p> <p>Tasks involved are, but not limited to:</p> <ul style="list-style-type: none"> • Database searches • Letter generation (packaging and postage excluded from fee and should be reimbursed as relevant to volume) • Patient follow-up including follow-up of non-responders (if covered in ethics application) • Tracking <p>The guide fee assumes standard charge for note searches but could increase for complex searches or requires large numbers of letter generated.</p> <p>The separate screening fee per randomised patient covers any source data verification work or support work the referral may require in relation to participation in the research. This should only be charged where additional work to that covered under the set-up tasks is required for the patient to participate</p>
NIHR_DEPT_009	Successful screening fee per randomised patient at PIC to be paid quarterly in arrears	General Departments	In Flight	£	52	
NIHR_DEPT_010	Refreshments for Patients (applicable for visits lasting over 3 hours) to be paid quarterly in arrears - Study Subject Related Expenses and Allowances	General Departments	In Flight	TBC		To be discussed directly between Sponsor and local site

NIHR_DEPT_011	Refreshments for Carers (applicable for visits lasting over 3 hours) to be paid quarterly in arrears - Study Subject Related Expenses and Allowances	General Departments	In Flight	TBC	To be discussed directly between Sponsor and local site
NIHR_DEPT_012	Inconvenience payment for patients as agreed by ethics to be paid quarterly in arrears - Study Subject Related Expenses and Allowances	General Departments	In Flight	TBC	To be discussed directly between Sponsor and local site
NIHR_DEPT_013	Maximum patient travel costs per visit* to be paid quarterly in arrears - Study Subject Related Expenses and Allowances	General Departments	In Flight	TBC	To be discussed directly between Sponsor and local site
NIHR_DEPT_014	Expenses for chief investigator attendance at Ethics meeting	General Departments	Setup	TBC	To be discussed directly between Sponsor and local site
NIHR_DEPT_015	Audiology Departments Setup	Audiology Departments	Setup	£ 260	Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.

NIHR_DEPT_016	Cardiovascular Departments Setup	Cardiovascular Departments	Setup	£ 260	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_017	Dental Departments Setup	Dental Departments	Setup	£ 260	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>

NIHR_DEPT_018	Genetics Departments Setup	Genetics Departments	Setup	£ 260	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_019	Immunology or Virology Departments Setup	Immunology or Virology Departments	Setup	£ 260	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>

NIHR_DEPT_020	Interventional Diagnostics Departments Setup	Interventional Diagnostics Departments	Setup	£ 260	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_021	Microbiology Departments Setup	Microbiology Departments	Setup	£ 260	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>

NIHR_DEPT_022	Nuclear Medicine Departments Setup	Nuclear Medicine Departments	Setup	£ 260	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_023	Ophthalmology Departments Setup	Ophthalmology Departments	Setup	£ 260	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>

NIHR_DEPT_024	Radiology Additional scanning reports (e.g. RECIST, iRECIST etc) to be paid quarterly in arrears	Radiology Departments	In Flight	£	133	
NIHR_DEPT_025	Radiology CRE Assessment	Radiology Departments	Setup	£	260	
NIHR_DEPT_026	Radiology MPE Assessment	Radiology Departments	Setup	£	260	
NIHR_DEPT_027	Radiology Phantom MRI Scans (inc Radiographer Training Time)	Radiology Departments	Setup	£	550	
NIHR_DEPT_028	Radiology Phantom CT Scans (inc Radiographer Training Time)	Radiology Departments	Setup	£	332	
NIHR_DEPT_029	Radiology Imaging Transfer to CD or Sponsor provided Soft or Hardware to be paid quarterly in arrears	Radiology Departments	In Flight	£	31	
NIHR_DEPT_030	Radiology extending working hours (per hour) to be paid quarterly in arrears	Radiology Departments	In Flight	£	75	Extended hours are defined as work added onto the normal working hours (09:00-17:00 Monday to Friday), but not necessarily starting in working hours, for example CT dispensing required on a Tuesday 17:00-18:30. Whereas out-of-hours work is defined as weekend work or late evenings not following on from normal working hours, for example CT dispensing on a Tuesday 20:00-21:30 or Saturday morning
NIHR_DEPT_031	Radiology CRA-requested dedicated Imaging staff time to support monitoring visits. Provision of basic access, hospitality, documentation provision and query response (per hour) to be paid quarterly in arrears	Radiology Departments	In Flight	£	75	

NIHR_DEPT_032	Radiology revision of relevant SOPs or Imaging documentation as a result of a substantial protocol amendment (per hour) to be paid quarterly in arrears	Radiology Departments	In Flight	£ 75	
NIHR_DEPT_033	Radiotherapy Setup	Radiotherapy Departments	Setup	£ 260	<p>Review protocol</p> <p>Feasibility assessment</p> <p>Communication with the sponsor</p> <p>Participation in mandatory local review and approval processes</p> <p>Attendance at meetings & liaison with PI, Research Nurse, CRA</p> <p>Write bespoke SOPs, associated documents and worksheets</p> <p>Set up dispensing & stock control software systems and documentation</p> <p>Set up supply systems</p> <p>Train all relevant departmental staff, as required</p> <p>Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>

NIHR_DEPT_034	Specialist Medicine Setup	Specialist Medicine Departments	Setup	£ 260	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_035	Pharmacy A: Dispensary based dispensing only with no aseptic dispensing	Pharmacy Departments	Setup	£ 1,680	<p>Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set-up electronic prescribing and Pharmacy systems, where applicable Set up supply systems Train all relevant Pharmacy staff, as required Review contract including pharmacy costing Close down. The base calculated figure is based upon 21.5 hours setup time</p>

					required by Managerial and administrative grade staff.
NIHR_DEPT_036	Pharmacy B: Aseptic dispensing only	Pharmacy Departments	Setup	£ 1,938	<p>Review protocol</p> <p>Feasibility assessment</p> <p>Communication with the sponsor</p> <p>Participation in mandatory local review and approval processes</p> <p>Attendance at meetings & liaison with PI, Research Nurse, CRA</p> <p>Write bespoke SOPs, associated documents and worksheets</p> <p>Set up dispensing & stock control software systems and documentation</p> <p>Set-up electronic prescribing and Pharmacy systems, where applicable</p> <p>Set up supply systems</p> <p>Train all relevant Pharmacy staff, as required</p> <p>Review contract including pharmacy costing</p> <p>Close down. The base calculated figure is based upon 25 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_037	Pharmacy C: Dispensary and aseptic dispensing	Pharmacy Departments	Setup	£ 2,326	<p>Review protocol</p> <p>Feasibility assessment</p> <p>Communication with the sponsor</p> <p>Participation in mandatory local review and approval processes</p> <p>Attendance at meetings & liaison with PI, Research Nurse, CRA</p> <p>Write bespoke SOPs, associated documents and worksheets</p> <p>Set up dispensing & stock control software systems and documentation</p> <p>Set-up electronic prescribing and Pharmacy systems, where applicable</p> <p>Set up supply systems</p>

					<p>Train all relevant Pharmacy staff, as required</p> <p>Review contract including pharmacy costing</p> <p>Close down. The base calculated figure is based upon 30 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_038	Pharmacy D: Cell based Gene Therapy setup	Pharmacy Departments	Setup	£ 30,000	<p>Review protocol</p> <p>Feasibility assessment</p> <p>Communication with the sponsor</p> <p>Participation in mandatory local review and approval processes</p> <p>Attendance at meetings & liaison with PI, Research Nurse, CRA</p> <p>Write bespoke SOPs, associated documents and worksheets</p> <p>Set up dispensing & stock control software systems and documentation</p> <p>Set-up electronic prescribing and Pharmacy systems, where applicable</p> <p>Set up supply systems</p> <p>Train all relevant Pharmacy staff, as required</p> <p>Review contract including pharmacy costing</p> <p>Close down. The base calculated figure is based upon 385 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_039	Pharmacy Set-up/close down for each additional site within the same NHS Trust (charged per site)	Pharmacy Departments	Setup	£ 198	<p>The base calculated figure is based upon 2.5 hours setup time required by Managerial and administrative grade staff.</p>

NIHR_DEPT_040	Pharmacy IMP Management Fee per year per site (Annualised charge - pro rata as needed) to be paid quarterly in arrears	Pharmacy Departments	In Flight	£ 570	<p>The IMP Management Fee is applicable to all studies requiring IMP management by an NHS Pharmacy. Full costs are chargeable unless Sponsor/CRO provide evidence and/ or information for specific Pharmacy requirements resulting in a suitable negotiated fee.</p> <p>Charged as an annual fee, which can be calculated pro rata as required, for the duration of the trial unless otherwise agreed and documented in the trial agreement.</p> <p>Stock checks are deemed part of routine standard practice, however any additional requirements (e.g. reporting or Company requested stock checks) may be charged as additional fees.</p> <p>Charged from month of site initiation visit to month of site close out visit. The following activities are included in as IMP Management Activities:</p> <p>Temperature management activities other than providing evidence of temperature to sponsors</p> <p>Temperature excursion management</p> <p>Expiry date checking</p>
NIHR_DEPT_041	Pharmacy Prescription Charge to be paid quarterly in arrears	Pharmacy Departments	In Flight	See note	Standard NHS Prescription charge to be added directly to contract if applicable
NIHR_DEPT_042	Pharmacy Storage space per month to cover charge incurred by Pharmacy for additional space within each NHS Trust regardless of temperature	Pharmacy Departments	In Flight	£ 52	

	requirements (per site charge as required)				
NIHR_DEPT_043	Pharmacy Receiving Shipment to be paid quarterly in arrears	Pharmacy Departments	In Flight	£ 52	
NIHR_DEPT_044	Pharmacy Waste disposal management inc paperwork, logs etc to be paid quarterly in arrears	Pharmacy Departments	In Flight	£ 42	
NIHR_DEPT_045	Pharmacy Packaging returns for return to sponsor to be paid quarterly in arrears	Pharmacy Departments	In Flight	£ 32	
NIHR_DEPT_046	Pharmacy Specialist storage requirements for advanced therapy/radiopharmaceuticals (e.g. dry shipper containing liquid nitrogen or minus 80C freezers) (per site charge as required) to be paid quarterly in arrears	Pharmacy Departments	In Flight	TBC	To be discussed directly between Sponsor and local site
NIHR_DEPT_047	Pharmacy Specialist transportation requirements for advanced therapy/radiopharmaceuticals (e.g. dry shipper, dry ice, spillage kits, courier costs) (per site charge as required) to be paid quarterly in arrears	Pharmacy Departments	In Flight	TBC	To be discussed directly between Sponsor and local site

NIHR_DEPT_048	Pharmacy Waste disposal storage pending collection or disposal of all medicines originally supplied by Sponsor per month or part thereof (per site charge as required). Chargeable only if not collected within 1 month of the first request to collect	Pharmacy Departments	In Flight	£	26	
NIHR_DEPT_049	Pharmacy Storage or disposal of all unused/expired medicines originally supplied by Sponsor. Chargeable if not collected within 1 month of the first request and to be paid per month quarterly in arrears.	Pharmacy Departments	In Flight	£	52	
NIHR_DEPT_050	Pharmacy Re-labelling and releasing of IMP batch (Usual staff hourly rate) to be paid quarterly in arrears	Pharmacy Departments	In Flight	£	78	
NIHR_DEPT_051	Pharmacy Extending working hours (Usual staff hourly rate + 50%) to be paid quarterly in arrears	Pharmacy Departments	In Flight	£	78	Extended hours are defined as work added onto the normal working hours (09:00-17:00 Monday to Friday), but not necessarily starting in working hours, for example CT dispensing required on a Tuesday 17:00-18:30. Whereas out-of-hours work is defined as weekend work or late evenings not following on from normal working hours, for example CT dispensing on a Tuesday 20:00-21:30 or Saturday morning
NIHR_DEPT_052	Pharmacy Out-of-hours working (Usual staff hourly rate + 100%) to be paid quarterly in arrears	Pharmacy Departments	In Flight	£	78	

NIHR_DEPT_053	Pharmacy Pharmacy staff time to support monitoring visits inc remote monitoring. Chargeable on an hourly rate to be paid quarterly in arrears	Pharmacy Departments	In Flight	£ 78	
NIHR_DEPT_054	Pharmacy IVRS/ study specific training as required by sponsor. Chargeable on an hourly rate. to be paid quarterly in arrears	Pharmacy Departments	In Flight	£ 78	
NIHR_DEPT_055	Pharmacy Individual training sessions for handling and preparation of study advanced therapy/radiopharmaceutical (usual staff hourly rate) to be paid quarterly in arrears	Pharmacy Departments	In Flight	£ 78	
NIHR_DEPT_056	Pharmacy Time to assess whether revision of relevant SOPs or IMP documentation is required as a result of a protocol, Investigational Brochure or pharmacy manual amendment (Usual staff hourly rate) to be paid quarterly in arrears	Pharmacy Departments	In Flight	£ 78	
NIHR_DEPT_057	Pharmacy Sponsor requested stock or temperature checks (Usual staff hourly rate) to be paid quarterly in arrears	Pharmacy Departments	In Flight	£ 78	
NIHR_DEPT_058	Pharmacy IMP release by Qualified Person (QP), if required (QP actual hourly rate) to be paid quarterly in arrears	Pharmacy Departments	In Flight	TBC	To be discussed directly between Sponsor and local site
NIHR_DEPT_059	Pharmacy Study or IMP specific consumables for Pharmacy (total cost) to be paid quarterly in arrears	Pharmacy Departments	In Flight	TBC	To be discussed directly between Sponsor and local site

NIHR_DEPT_060	Pharmacy Equipment purchase for specific IMP requirements in storage space or conditions (total cost) to be paid quarterly in arrears	Pharmacy Departments	In Flight	TBC	To be discussed directly between Sponsor and local site
NIHR_DEPT_061	Device/ Clinical Equipment Courier/ posting costs for IMPs (third party costs as required e.g. per patient, sponsor returns) to be paid quarterly in arrears	Pharmacy Departments	In Flight	TBC	To be discussed directly between Sponsor and local site
NIHR_DEPT_062	Device/ Clinical Equipment A: Supply or device is to be checked and reviewed by only the research team	Device/ Clinical Equipment	Setup	£ 71	
NIHR_DEPT_063	Device/ Clinical Equipment B: Consultation with only one Trust service support department or other provider (e.g., Medical Physics, Electrical Engineering, Lab Based Medicines or Other specialists departments or providers)	Device/ Clinical Equipment	Setup	£ 142	
NIHR_DEPT_064	Device/ Clinical Equipment C: Consultation with more than one department	Device/ Clinical Equipment	Setup	£ 211	
NIHR_DEPT_065	Device/ Clinical Equipment D: No consultation with research staff required	Device/ Clinical Equipment	Setup	TBC	To be discussed directly between Sponsor and local site

NIHR_DEPT_066	Device/ Clinical Equipment Device Management Fee per month per site to be paid quarterly in arrears	Device/ Clinical Equipment	In Flight	£ 75	The Trial Maintenance Activities fee covers: Routine stock checks Stock and accessory ordering and invoicing Device maintenance Contenting for device failure, malfunction, removal and returns Equipment sterilisation Regular checking and testing of equipment Maintaining the accountability log Tracking of device Communications with the company
NIHR_DEPT_067	Pathology Setup	Pathology Departments	Setup	£ 260	Review protocol Feasibility assessment Communication with the sponsor Participation in mandatory local review and approval processes Attendance at meetings & liaison with PI, Research Nurse, CRA Write bespoke SOPs, associated documents and worksheets Set up dispensing & stock control software systems and documentation Set up supply systems Train all relevant departmental staff, as required Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.

NIHR_DEPT_068	Radiology Setup	Radiology Departments	Setup	£ 260	<p>Review protocol</p> <p>Feasibility assessment</p> <p>Communication with the sponsor</p> <p>Participation in mandatory local review and approval processes</p> <p>Attendance at meetings & liaison with PI, Research Nurse, CRA</p> <p>Write bespoke SOPs, associated documents and worksheets</p> <p>Set up dispensing & stock control software systems and documentation</p> <p>Set up supply systems</p> <p>Train all relevant departmental staff, as required</p> <p>Close down. The base calculated figure is based upon 7.5 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_069	Pharmacy Specialist profession oversight fee for advanced therapies or radiopharmaceuticals. Annulised charge pro rata as needed	Pharmacy Departments	Setup	TBC	To be discussed directly between Sponsor and local site

NIHR_DEPT_070	National Co-Ordinator Fee	General Departments	Setup	£ 359	<p>National review of study requirements based on protocol and submitted documentation including clarification on missing or ambiguous requirements.</p> <p>Discussion with CI/ teams as to results of initial assessment and adjustments made based on clinical expertise on protocol</p> <p>Discussion of results obtained from initial assessment with Sponsor or company representative</p> <p>Provision of general support for Sponsor to understand the requirements in the context of UK research environment. Local CRN team is available to provide support as required (link to contacts on website)</p> <p>Variations to value (increase or decrease) may occur in relation to study or therapy area complexity. The base calculated figure is based upon 10 hours setup time required by Managerial and administrative grade staff.</p>
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NIHR_DEPT_071	General R&D Fee for studies going through National Coordination	General Departments	Setup	£ 849	<p>Costing and model agreement negotiation across organisation for final agreement, including any sub-contracts/service level agreement/honorary contracts as required.</p> <p>Coordination of practical arrangements for confirmation of local capability and capacity across the organisation as required by HRA Approval. Further information is available in the CRN principles of good practice (link to be included to document). NOTE: Assessment is considered part of site selection and covered by the indirect and capacity building elements of the template.</p> <p>Research management activities, such as investigator file set-up and maintenance, including performance oversight for set-up and recruitment activities to deliver contracted requirements.</p> <p>Co-ordination of all close-down activities across the organisation to met Sponsor requirements. The base calculated figure is based upon 26 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_072	Pharmacy E: Virus based Gene Therapy setup	Pharmacy Departments	Setup	£ 8,000	<p>Review protocol</p> <p>Feasibility assessment</p> <p>Communication with the sponsor</p> <p>Participation in mandatory local review and approval processes</p> <p>Attendance at meetings & liaison with PI, Research Nurse, CRA</p>

					<p>Write bespoke SOPs, associated documents and worksheets</p> <p>Set up dispensing & stock control software systems and documentation</p> <p>Set-up electronic prescribing and Pharmacy systems, where applicable</p> <p>Set up supply systems</p> <p>Train all relevant Pharmacy staff, as required</p> <p>Review contract including pharmacy costing</p> <p>Close down. The base calculated figure is based upon 102 hours setup time required by Managerial and administrative grade staff.</p>
NIHR_DEPT_073	Pharmacy F: Somatic Cell Therapy setup	Pharmacy Departments	Setup	£ 20,000	<p>Review protocol</p> <p>Feasibility assessment</p> <p>Communication with the sponsor</p> <p>Participation in mandatory local review and approval processes</p> <p>Attendance at meetings & liaison with PI, Research Nurse, CRA</p> <p>Write bespoke SOPs, associated documents and worksheets</p> <p>Set up dispensing & stock control software systems and documentation</p> <p>Set-up electronic prescribing and Pharmacy systems, where applicable</p> <p>Set up supply systems</p> <p>Train all relevant Pharmacy staff, as required</p> <p>Review contract including pharmacy costing</p> <p>Close down. The base calculated figure is based upon 256 hours setup time required by Managerial and administrative grade staff.</p>

NIHR_DEPT_074	Pharmacy G: Tissue engineered product setup	Pharmacy Departments	Setup	£ 20,000	<p>Review protocol</p> <p>Feasibility assessment</p> <p>Communication with the sponsor</p> <p>Participation in mandatory local review and approval processes</p> <p>Attendance at meetings & liaison with PI, Research Nurse, CRA</p> <p>Write bespoke SOPs, associated documents and worksheets</p> <p>Set up dispensing & stock control software systems and documentation</p> <p>Set-up electronic prescribing and Pharmacy systems, where applicable</p> <p>Set up supply systems</p> <p>Train all relevant Pharmacy staff, as required</p> <p>Review contract including pharmacy costing</p> <p>Close down. The base calculated figure is based upon 256 hours setup time required by Managerial and administrative grade staff.</p>
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