NCVR Study Resource Review checklist

IRAS/CPMS and/or Title	

Helpful Information
This checklist is designed to support national reviewers in conducting a thorough study resource review and contains the key items to consider. It is not exhaustive, and reviewers should consult the guidance documents available in the Teams Community of Practice (request access via your CRN representative) in addition to ensure content is as accurate as possible. Helpful links: How the interactive Costing Tool (iCT) calculates the costs of studies at sites | NIHR iCT Tariff data: How the interactive Costing Tool (iCT) calculates the costs of studies at sites | NIHR **NB. This list is not exhaustive and does not negate the Study Resource Reviewer needing to understand the study protocol requirements and ensure that is is costed appropriately.**

Review	Validation Check	Comments
Documents received for review	In addition to protocol (including schedule of events SoE) request pharmacy/lab/imaging manuals if appliable to support costing review (note, if the manuals are not available, please request the specific information that you require to complete the review). • Protocol • Pharmacy/Lab/Imaging manuals	

	• IRAS Form (including Ionising Radiation Section if applicable) * it may be helpful to also request a copy of the data entry / eCRF requirements to determine the data entry requirements	
Completion status	The study interactive costing tool (iCT) has been populated with all study specific information to review. Where no information has been included within the tool i.e. the tables are blank or have minimal content that is disproportionate to the study requirements, the Study Resource Reviewer should revert the study back to the company representative in CPMS. Please discuss this with your Local CRN in advance.	
Chief Investigator (CI) Agreement	Ensure that a separate CI Agreement is in place and that no CI activity is included in the iCT.	
Per patient budget (may be labelled as study arm(s))	• Number of visits and arms (e.g. long-term follow-up) included and named as per the protocol/schedule of events. For multiple arms, additional arms should be displayed within the iCT. • Visits should not be grouped together as one visit (*this will impact the per patient total and financial appendix). • All tasks are included as required in the sections for procedures *(time-based activities)* and investigations *(activities including a combination of equipment and staff time)* ideally reflecting the terminology and order of the protocol/ SoE (*clinical review of timings is required by Ci/PI/Clinical delivery teams). • All line items have times or prices values assigned, if tariff states 'TBC', Study Resource Reviewer should determine the value. • Correct activities and number of activities (E.g. 2 x vital signs or PK sampling) included for the correct corresponding visits.	

	• Review of any footnotes or associated narrative within the schedule of events which can affect the information included. Items flagged as optional in the footnotes within the SoE should be added to the Unscheduled Activities.
	
	• If possible from the SoE, identify any grouped or multi activities named as one procedure e.g. multiple questionnaires or multiple vital signs before, during and after infusions. Include as separate procedures as required.
	
	<u>Costs to include in per patient budget section:</u>
	
	• Any overnight stays if identified from the schedule of events. (NIHR_INV_002/003) (NP_010/016). *Please note, some investigations also include an overnight stay, always check the definition of the tariff.
	
	• CRF/eCRF completion or transcription time with CRF sign off (which may be a different line item if performed by another staff role) (NIHR_PRC_026).
	
	• Monitoring visit per patient visit (NIHR_PRC_030) (may alternatively be included in Unscheduled Activities or in Set-up/Close down.)
	
	• Sample preparation/blood sample preparation e.g. for central analysis
	  ◦ Blood sample – collection only (NIHR_PRC_004)
	  ◦ Blood sample – collection processing (NIHR_PRC_005)
	  ◦ Specimen dispatch by post/courier (if local labs, this is not applicable and pathology tests should be included) (NIHR_PRC_006).
	
	• Lab kit storage (NIHR_DEPT_081).
	
	• Provision of instructions, user training, transcription and review of any patient diaries (including e-diaries) or questionnaires:
	  ◦ Dispense diaries and instruct (NIHR_PRC_023) - to be added at first visit.
	  ◦ Collect and review diaries (NIHR_PRC_024) - to be added at all subsequent visits as per the Schedule of Events.
	  ◦ Subject Questionnaire (NIHR_PRC_017) - increase occurrences depending on number of questionnaires in schedule of events.	

	• Review Questionnaire (NIHR_PRC_018) - increase occurrences depending on number of questionnaires in schedule of events. • Review/reporting of participant AEs/SAEs - ensure sufficient time is included to cover SAE review unless SAE review added separately in Unscheduled Activities (NIHR_PRC_027). • Handover to routine care (End of Trial) (NIHR_PRC_028). • Randomisation (manual, IVRS or IWRS) (NIHR_PRC_015). • Urinalysis • Urinalysis - Urine collection only (at clinic) (NIHR_PRC_012) • Urinalysis - Urine processing (dipstick or sample preparation) (NIHR_PRC_012). • Pharmacy dispensing (and associated costs) • Dispensing – to be confirmed with pharmacy (NIHR_PRC_033/ 034/ 035). • Use of IVR/IWR system (only chargeable if performed by Pharmacy) (NIHR_PRC_037). • Individual participant drug accountability time (NIHR_PRC_039). • Administer study drug in clinic (NIHR_PRC_022) (if applicable) • If drug given to patients to administer at home, add: Instructions/education for participant and/or care giver (NIHR_PRC_016). • Dissemination of study results to participants (NIHR_PRC_031). • Biopsies and archival tissue NIHR_PRC_047 Archival Tissue Retrieval	

	NIHR_INV_117 Tissue acquisition/banking – fresh/frozen/FFPE per sample NIHR_INV_118 Tissue processing to FFPE only – per block NIHR_INV_119 FFPE standard blaock sectioning – per tissue section NIHR_INV_122 H&E staining of FFPE and frozen sections – per tissue section NIHR_INV_123 Special Stains per tissue section NIHR_INV_124 Retrieval per slide and block (1 unit) NIHR_INV_125 Retrieval of slides and blocks (up to 5 units) NIHR_INV_126 Retrieval of slides and bloacks (up to 10 units) NIHR_INV_127 Slide Scanning x 20 mag – per slide NIHR_INV_128 Slide Scanning x 40 mag – per slide ● On Call fees if mandated by the Protocol. Not currently available within the standard tariff. ● Daily Facility Charge (refer to tariff definition) (NIHR_INV_001_NP009). **ATMP/Early Phase Studies** ● Ensure the GP Eligibility Letter fee (NIHR_PRC_054) for applicable studies. Where used add the GP Eligibility Letter – Return of Medical history fee (NIHR_INV_189) to unscheduled activities to cover any GP costs. ● ATMP Referral Management fee (NIHR_GPC_072) to cover where external patients are referred to the main research site. ● Cellular therapy trials should have the new Cellular Therapy set-up fee (NIHR_GPC_073) ● Phase 1 study new (TOPs) registration fee (NIHR_PRC_059)	
Unscheduled Activity	● Any activities which may occur at unscheduled time points are included (e.g. extra lab tests or unscheduled x-rays) individually: ● All local lab tests ● Blood sample collection, processing and shipment (if applicable)	

	• All imaging/scans and reporting fees • Urinalysis – collection and processing • Pregnancy tests (serum and urine as applicable). • Additional Safety reports and AE/SAEs tasks. • Monitoring visit support time (NIHR_PRC_044 or NIHR_GPC_017) (also may be included in the per patient or Set-up/Close Down section). • Hourly Training fee (clinical and nurse) - to cover any additional training including amendments. Recommend using (NIHR_GPC_016) but amend the time accordingly. • Re-consenting (NIHR_PRC_043). • SAE Reporting (recommend adding non-tariff item for SAE reporting only if study demands are different to normal review). • Pharmacy dispensing and associated costs. • All activities included in Screening Visit (for re-screening and screen failures). • All activities that may be required in an Unscheduled Visit. **ATMP/Early Phase studies** • Daily Facility Charges should be added (either paediatric or adult) depending on the study) (NIHR_INV_001 and NP009) • Overnight facility charges should always be added (NP010 or NP010). Paediatric charges are NIHR_INV_002 and NIHR_INV_003	
Pharmacy Activity	• All per patient study drug and comparator activity have a corresponding entry within the per patient section. • Number of visits for dispensing is correct for per patient section.	

	• Non-interventional IMP/Standard of Care drug reimbursement add to Unscheduled Activities at zero cost (*add to description “plus BNF rate +VAT”).
	
	• Set-up section:
	  • Relevant set-up fee (NIHR_GPC_029/030/031/032/033/036/037/038).
	  • Account for storage
	  • Pharmacy storage space per month to cover additional space within each NHS Trust regardless of temperature requirements, monthly fee (annualised charge pro rata as needed) (NIHR_DEPT_042/ 046/060).
	  • Account for shipment
	  • Pharmacy receiving shipment, per occurrence (chargeable quarterly in arrears) (NIHR_DEPT/ 043).
	  • Account for waste
	  • Pharmacy waste disposal management including paperwork, logs etc, per occurrence (chargeable quarterly in arrears) (NIHR_DEPT_044).
	  • Waste disposal as hazardous waste per container or Investigational Medicinal Product (IMP) destruction (chargeable quarterly in arrears) (NIHR_DEPT_048).
	  • Account for storage of expired stock
	  • Pharmacy storage or disposal of 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 (NIHR_DEPT_049).
	  • Pharmacy monitoring, audit, and training	

	● Pharmacy presence at monitoring, audit or training visits, including remote monitoring (chargeable at the end of each visit) (NIHR_GPC_047). ● Pharmacy Interactive Voice Response (IVR) system/ study specific training as required by Sponsor (chargeable quarterly in arrears) (NIHR_GPC_065/066). ● Pharmacy revision of SOPs ● Pharmacy revision of relevant Standard Operating Procedures (SOPs) or documentation as a result of a protocol, Investigational Brochure or pharmacy manual amendment (chargeable at each amendment) (NIHR_GPC_049). ● Electronic prescription build fee (NIHR_GPC_067). ● Pharmacy packaging returns for return to Sponsor, per occurrence (chargeable quarterly in arrears) (NIHR_DEPT_045). ● IMP Management Fee per year per site (Annualised charge - pro rata as needed) (NIHR_DEPT_040). ● Set-up/close down for each additional site within the same NHS Trust (charged per site). ● Pharmacy re-labelling and releasing of Investigational Medicinal (NIHR_GPC_063). ● Product (IMP) batch (chargeable quarterly in arrears). ● Pharmacy Sponsor requested stock or temperature checks (chargeable quarterly in arrears) (NIHR_GPC_067). ● Are other Pharmacy set-up fees recorded within tariff considered? (e.g. Homecare NIHR_GPC_040).	
Radiology Activity	● Radiology set-up fee (NIHR_GPC_035).	

	• Radiology presence at monitoring, audit or training visits (chargeable at the end of each visit) (NIHR_GPc_046).
	• Radiology revision of relevant SOPs or Imaging documentation (NIHR_GPC_048).
	• Radiology Clinical Radiation Expert (CRE) assessment (*add both CRE and MPE tariffs) (NIHR_DEPT_025/026).
	• Radiology Medical Physics Expert (MPE) assessment (NIHR_DEPT_026).
	• Administration of Radioactive Substances Advisory Committee (ARSAC) local approval may be required, this would need to be added as non-tariff.
	• Copies of Diagnostic Films, Simple (e.g. x-rays) - Per Copy (NP013), complex (NP014).
	• Image transfer (consider time required to complete this and add as non-tariff item).
	• Relevant reporting fee for every scan included:
	  o Normal/standard clinical report: NIHR_INV_051.
	  o Complex report (including but not limited to reports with RECIST/iRECIST, Cheson/Lugano, RAMRIS, MY-RADS classification: NIHR_INV_051 and NIHR_INV_024.
	• Phantom scan requirement, if needed add relevant set-up cost (NIHR_DEPT_027/028).	

Set-up and Close Down	• Add R&D fee aligning to tier from the tariff (NIHR_GPC_015/ 060/ 061). • Set-up fees for any additional support departments as required (Please refer to the iCT tariff for a list of the support department	

	fees, however this list isn't exhaustive, therefore department set up fees can be added manually if protocol dictates). ● Training (i.e. SIV) - Daily training fee – to cover SIV (NIHR_GPC_016). ● Monitoring (NIHR_PRC_044 or NIHR_GPC_017) (also may be included in the per patient or Unscheduled Activity). ● Amendments (NIHR_GPC_045). ● PIC *if applicable aligning to the relevant tier from the tariff (NIHR_GPC_018), (NIHR_GPC_043), (NIHR_GPC_44). ● PIC Screening fee (NIHR_GPC_019). ● Non-triggered sponsor/CRO audit (NIHR_GPC_039). **ATMP/Early Phase Studies** ● Assess to see if Tier 4 R&D Set-up fee is appropriate to use ● Annual Safety Maintenance fee (NIHR_GPC_081)	
Pass-through costs	● The following items will be documented within the Financial Appendix, to be considered locally: ● Patient travel, refreshments/expenses, accommodation, inconvenience payments. ● Archiving (no fee is actually specified in the financial appendix; this is determined at the end of study).	
Summary sheet	Confirm totals are displayed from the individual sheets.	
Completion	Ensure any changes are fully commented upon and that a comment flag appears within the iCT to denote that a change and comment has been made. Study Resource Reviewer ticked 'Mark as Complete' to allow iCT to be released to sponsor/CRO for review. Further reviews/comments may be required before the iCT is considered 'validated' and the budget agreed.	