**[Financial Arrangements Appendix Instructions**

*Please delete instruction text prior to sharing the Agreement with the Trial Site.*

* *Clause 2.2: Three options, to describe the arrangements for raising invoices for this Clinical Trial, are provided to the Sponsor, or party acting on its behalf. The applicable option should be retained and the two other options deleted. Brackets and yellow highlights should be removed prior to sharing the Agreement with the Trial Site.*
* *Clause 6.5: This is an optional clause for use when the Sponsor, or party acting on its behalf, intends to provide a float to the Trial Site to allow for Trial Site payment of Clinical Trial Participant expenses* (and, as applicable, expenses for parents, carers or others who may reasonably be expected to accompany Clinical Trial Participants). If no float is to be provided, Clause 6.5 should be deleted prior to sharing the Agreement with the Trial Site. If a float is to be provided, the value of this float in GBP should be inserted into this clause and brackets and yellow highlights removed prior to sharing the Agreement with the Trial Site.
* *Clause 7.1: Two options are provided for archiving of Trial Site study data: a. ‘on-site’ archiving arranged by the Trial Site, b. ‘off-site’ archiving arranged by the Sponsor, or party acting on its behalf. The applicable option should be retained and the other option deleted prior to sharing the Agreement with the Trial Site. The Sponsor may need to discuss which option is most appropriate for the Trial Site, with the Trial Site, prior to sharing the Agreement. The fields identifying the archiving contact at the Trial Site may be completed by the Sponsor, or party acting on its behalf, following discussion with the Trial Site and prior to sharing the Agreement with the Trial Site, or they may be completed by the Trial Site after receiving the Agreement and prior to contract execution. Brackets and yellow highlights should be removed prior to contract execution.*
* *Clause 9.1.1: Two options are presented for calculating payments for screen-failures. The option chosen by the sponsor should be retained and the other deleted. If the option chosen is payment of a percentage of the visit-one fee, the Sponsor should state the percentage in the brackets within the clause prior to sharing the Agreement with the Trial Site. Brackets and yellow highlights should be removed prior to sharing the Agreement with the Trial Site.*
* *Clause 14.1: The Sponsor, or party acting on its behalf, should provide here the contact details to which invoices should be sent by the Trial Site. The Sponsor may state here whether their preference is to receive invoices physically at this address or by email. The physical address should be provided regardless. Yellow highlight should be removed prior to sharing the Agreement with the Trial Site.*
* *Clause 14.2: The contact details for invoice queries to be sent to the Trial Site may be completed by the Sponsor, or party acting on its behalf, following discussion with the Trial Site and prior to sharing the Agreement with the Trial Site, or they may be completed by the Trial Site after receiving the Agreement and prior to contract execution. Whether the Trial Site chooses to receive the queries to its physical address or by email may be specified here. Brackets and yellow highlights should be removed prior to contract execution.*
* *Clause 14.3: Payment details for the Trial Site may be completed by the Sponsor, or party acting on its behalf, following discussion with the Trial Site and prior to sharing the Agreement with the Trial Site, or they may be completed by the Trial Site after receiving the Agreement and prior to contract execution. Brackets and yellow highlights should be removed prior to contract execution.*
* *Clause 15: The iCT generated Finance Schedule should be inserted here, after completion of iCT study resource review and prior to sharing the Agreement with the Trial Site. No modifications to the Finance Schedule should be made by either Party.*

***END OF INSTRUCTIONS****]*

# Appendix 4 – Financial Arrangements

1. **Payments**
	1. This Appendix specifies all payments to be made by, or on behalf of, the Sponsor, to the Trial Site, under the Financial Arrangements and Termination Clauses within this Agreement.
	2. Clinical Trials that are subject to [National Contract Value Review](https://www.england.nhs.uk/aac/what-we-do/embedding-research-in-the-nhs/national-contract-value-review/) must use an unmodified version of the Finance Schedule generated by the interactive Costing Tool (iCT). Changes, by either Party, to the Finance Schedule, prior to the Effective Date of this Agreement, are not permitted under the terms of the [National Directive on Commercial Contract Research Studies](https://www.england.nhs.uk/publication/national-directive-on-commercial-contract-research-studies/), in England, and equivalent policy positions in each of the devolved administrations.
		1. In accordance with the above, the Sponsor represents and warrants that the Finance Schedule, incorporated into this Appendix by or on behalf of the Sponsor, is an unmodified version of the Finance Schedule generated by the interactive Costing Tool (iCT) for this Clinical Trial, following the conclusion of the study resource review.
		2. In accordance with the above, the Trial Site represents and warrants that prior to contract execution, no alterations have been made to the Financial Arrangements Appendix, including the Finance Schedule, provided by or on behalf of the Sponsor.
2. **Invoicing and Value Added Tax (VAT)**
	1. Invoices will be based on the services performed and/or data monitored. Where possible, data will be confirmed as complete and evaluable in a timely manner by (or on behalf of) the Sponsor for the invoice period, prior to the raising of the invoice. No payment will be made by or on behalf of the Sponsor until a valid invoice for the amount payable has been received.
	2. [**OPTION 1, DELETE OPTIONS 2 AND 3 -** The Sponsor, or party acting on its behalf, will issue invoice requests, detailing visits and any additional procedures completed, on a quarterly basis from the Effective Date of this Agreement. The Trial Site shall invoice the Sponsor, or party acting on its behalf, in arrears upon receipt of an invoice request.] [**OR**] [**OPTION 2, DELETE OPTIONS 1 AND 3 -** Sponsor will liaise with Trial Site on a quarterly basis to agree the value and content of invoices to be raised] [**OR**] [**OPTION 3, DELETE OPTIONS 1 AND 2 -** The Sponsor, or party acting on its behalf, will use a self-invoicing system to raise invoices on a quarterly basis on behalf of the Trial Site]. Payments will be made in arrears within forty-five (45) days of the date of receipt of a valid invoice (excluding disputed amounts, which will be resolved in good faith in a timely manner in accordance with Clause 2.5 of this Appendix).
	3. Valid invoices issued by the Trial Site shall:
		1. be valid tax invoices for the purposes of VAT legislation;
		2. identify the Trial Site;
		3. contain a breakdown of fees per activity covering:
			1. set-up and close-down fees;
			2. Per Clinical Trial Participant fees, clearly identifying the correct Clinical Trial Participant identification number(s), and;
			3. all other fees.
		4. Clearly state the corresponding period being invoiced for any periodic fees (for example, IMP management fee);
		5. Identify the purchase order number assigned to the Clinical Trial;
		6. contain all other information as instructed by the Sponsor, or party acting on its behalf, including a copy of the relevant Sponsor invoice request, where applicable; and
		7. be sent to the Sponsor, or party acting on its behalf, at the email address provided below.
	4. The Trial Site’s failure to comply with the above invoice requirements may result in a delay in payment.
	5. Any delay in the payment of the payee invoices by or on behalf of the Sponsor will incur an interest charge on any undisputed amounts overdue of two (2) per cent per month above the National Westminster Bank plc base rate prevailing on the date the payment is due.
	6. If the Sponsor, or party acting on its behalf, disputes any invoice, or part of any invoice, or receives an invoice in respect of activities not provided in accordance with this Agreement, or which Sponsor believes (acting reasonably) have not been properly provided, then the Sponsor or the party acting on its behalf may either:
		1. withhold payment of the disputed part of the invoice in respect of the disputed amounts and/or activities, in which case the Trial Site shall issue the Sponsor, or the party acting on its behalf, with a credit note for the disputed amount and the Sponsor or the party acting on its behalf will pay the undisputed amount in accordance with the Financial Arrangements clause of this Agreement, or;
		2. reject the Trial Site’s invoice and request that the Trial Site submit a new invoice for the undisputed amount. On receipt of the new valid invoice, the Sponsor or the party acting on its behalf shall pay the new invoice in accordance with the Financial Arrangements clause of this Agreement.
	7. Any outstanding dispute remaining in relation to Clause 2.6 of this Appendix will be resolved in accordance with Clause 19 of this Agreement.
	8. The Sponsor will notify the Trial Site of Investigator Site Trial Completion, or early termination of the Agreement, in order to trigger the generation of a final invoice.
	9. Upon Investigator Site Trial Completion, or early Termination of the Agreement, all remaining amounts due shall be invoiced as per the terms detailed in this Financial Arrangements Appendix, subject to the following:
		1. completion of the close-out visit, where applicable;
		2. receipt of all completed and corrected case report forms and queries;
		3. receipt of the Principal Investigator’s final report, where applicable, in a form acceptable to Sponsor as per relevant standards/requirements, and;
		4. provided all unused Investigational Medical Product and any applicable Sponsor or Vendor Resources of Equipment has been accounted for.
	10. The Sponsor shall promptly respond to any reasonable request for invoicing data received from the Trial Site for the purposes of the final invoice, provided that the request is received within forty-five (45) days of the notification of Investigator Site Trial Completion or early termination of the Agreement.
	11. **Longstop Dates**
	It is agreed that the Sponsor shall not be required to make payment for any amounts that the Trial Site fails to notify the Sponsor of within sixty (60) days of the Sponsor providing the final invoicing information (if requested), in accordance with Clause 2.10 of this Appendix, or sixty (60) days from Investigator Site Trial Completion, or early termination of this Agreement, if invoicing information is not requested (“**Longstop Dates**”). For the avoidance of doubt, it is not an obligation for the Sponsor to pay invoices dated after the Longstop Date.
	12. The final invoice payment may be held by the Sponsor, or the party acting on its behalf, until all outstanding queries have been resolved.
	13. All figures in the Finance Schedule are INCLUSIVE of all indirect costs, capacity building and Trial Site specific multipliers, where applicable. All figures are EXCLUSIVE of VAT.
3. **Pass-through Payments**
	1. It shall be the responsibility of the Trial Site to make any appropriate agreed pass-through payments, such as payments to the Principal Investigator’s principal employer and/or any Participant Identification Centres or Other Trial Sites.
4. **Inflation**
	1. Adjustment to the Finance Schedule to account for inflation (‘**Adjustment’**) may be undertaken, at Trial Site request or as initiated by the Sponsor, a minimum of two years (twenty-four consecutive months) from the Effective Date of the Agreement and thereafter every twelve months.
		1. The prices presented in the revised Finance Schedule, accounting for inflation, will be the prices generated by the interactive Costing Tool (iCT) on the day agreed by the Parties and will be applied to all remaining Clinical Trial payments, excluding payments for visits and other activities that occurred prior to the sharing of the revised Finance Schedule by or on behalf of the Sponsor with the Trial Site.
		2. The iCT Finance Schedule generated on the day agreed, will be provided by the Sponsor to the Trial Site and incorporated into this Agreement, with subsequent invoices reflecting the uplifted Finance Schedule, subject to Clause 4.1.1 of this Appendix.
		3. For the avoidance of doubt, an Adjustment, to take account of inflation in line with this clause 4.1, is not a contract variation, amendment or modification and is not subject to Clause 1.3 of this Appendix or the Notices section of this Agreement.
5. **Set-up, Management and Close-down Fees**
	1. The one-off payments described in the tables under Clause 15.1 of this Appendix (Set-up, Management and Close-Down Fees) are non-refundable and will be payable upon execution of the Agreement (unless otherwise noted in the Task Breakdown).
6. **Clinical Trial Participant Related Expenses and Allowances**
	1. The Sponsor, or the party acting on its behalf, agrees to reimburse reasonable travel and other expenses, including refreshment costs, which occur as a direct result of participation in this Clinical Trial, including expenses incurred by Clinical Trial Participants and, as applicable, their parents, carers or others who may reasonably be expected to accompany Clinical Trial Participants.
	2. Reasonable expenses include standard class public transport, licensed hackney carriages/private hire vehicles (taxis) and use of a private vehicle (the latter at 45p per mile). Higher values are required to receive written approval from The Sponsor, or the party acting on its behalf, wherever possible PRIOR to travel expenditure being incurred.
	3. Clinical Trial Participants (and, as applicable, parents, carers or others who may reasonably be expected to accompany Clinical Trial Participants) should submit receipts, or other appropriate documentation, where available, to the Trial Site to support the expenditure. The Trial Site will reimburse Clinical Trial Participants (and, as applicable, parents, carers or others who may reasonably be expected to accompany Clinical Trial Participants) directly for travel and other expenses incurred, including refreshment costs.
	4. The Principal Investigator and Personnel will maintain records, supported by receipts of the expenditures where possible, and make de-identified copies available at monitoring visits, if requested. The Sponsor, or the party acting on its behalf, will reimburse the Trial Site for all such payments upon confirmation of spend and itemised inclusion in the quarterly invoice.
	5. [**DELETE IF NOT APPLICABLE** - If required, a travel float of £[XX.XX] will be provided and replenished as necessary by the Sponsor, or the party acting on its behalf, upon receipt of invoice from the Trial Site. Any balance remaining in the float at the end of the Clinical Trial will be refunded to the Sponsor, or the party acting on its behalf.]
7. **Archiving of Clinical Trial documents**
	1. [**OPTION 1 – DELETE OPTION 2** - Independent, secure archiving of the Clinical Trial documentation (including but not limited to Investigator Site files) will be arranged and funded by the Sponsor, or the party acting on its behalf,] [**OPTION 2 – DELETE OPTION 1** – The sponsor, or party acting on its behalf, will fund, in accordance with this Financial Arrangements Appendix, Trial Site archiving of the Clinical Trial documentation (including but not limited to Investigator Site files)] following Investigator Site Trial Completion, and in accordance with the [MRC Principles and Guidelines for Good Research Practice](https://www.ukri.org/publications/principles-and-guidelines-for-good-research-practice/).   This funding includes all preparation and retrieval fees relating to any reasonable request to access the Clinical Trial documentation.  All arrangements for access to documents at the Trial Site should be made with the Trials Site’s responsible person for archiving:

|  |  |
| --- | --- |
| Name: | [] |
| Job title: | [] |
| Email: | [] |

1. **Clinical Trial Participant Visit Fees**
	1. Payments will be made on a pro-rata basis according to the visit and investigation payments set out in Clause 15.2 of this Appendix (Clinical Trial Participant Visit Fees) and include all indirect costs, capacity building and applicable Trial Site specific multipliers.
	2. Please note that additional tables may have been added below, as a result of the study resource review, for unscheduled activities that may occur for selected Clinical Trial Participants only. This table will indicatively state the additional visit costs applicable for those selected Clinical Trial Participants.
2. **Payment for screen failure and discontinuation**
	1. For the purpose of this Appendix, a ‘**Screen Failure**’ is defined as a Clinical Trial Participant who is eligible with respect to Protocol defined eligibility criteria to enter the screening process, gave informed consent but is found to be ineligible for treatment allocation.
		1. All costs associated with each Screen Failure are payable by the Sponsor, or the party acting on their behalf, [**OPTION 1, DELETE OPTIONS 2 -** on a pro rata basis as per the individual task price set out in the below Finance Schedule] [**OR**] [**OPTION 2, DELETE OPTION 1 -** at the agreed screen failure payment rate of [**XX**]% of the agreed visit 1 price].
		2. The Sponsor, or the party acting on their behalf, is not expected to pay for recruited Clinical Trial Participants who did not meet the initial eligibility criteria to enter the screening process, or where there are significant deviations from the Protocol.
	2. A Clinical Trial Participant who discontinues from the Clinical Trial, prior to completion of all the Protocol defined visits and assessments, because of adverse events, inefficacy of IMP, coexistent disease, as a result of a decision made by the Principal Investigator and/or non-compliance or non-attendance, will be considered evaluable and payment will be made on a pro-rata basis.
	3. The value of payments under Clause 9.2 of this Appendix will be based on completion of visits, procedures and investigations as defined in the Participant table in this Appendix to cover all relevant costs and pass-through expenses in respect of such Clinical Trial Participants, provided that the data relating to such Clinical Trial Participants are adequately recorded in the Case Report Forms up to the time of discontinuation.
	4. Clinical Trial Participants who are entered into the Clinical Trial but who do not satisfy the Protocol eligibility criteria at the time of entry must be either discontinued from the Clinical Trial or dealt with as outlined in the Protocol. Appropriate payment, if applicable, will be agreed on a case by case basis between the Sponsor, or the party acting on their behalf, and Trial Site at the time of occurrence in respect of such Clinical Trial Participants.
3. **Unscheduled Visits**
	1. Unscheduled visits and unscheduled events, that are not already captured in the Finance Schedule, will be paid at the price for the relevant procedures and investigations set out in the version of iCT current at the time of the visit or event, with relevant Trial Site specific multipliers added.
4. **Central Laboratory Costs**
	1. Any central laboratory costs will be paid for by the Sponsor and have been excluded from this Agreement.
5. **All Other Fees**
	1. All other remaining fees not previously listed are included in Clause 15.3 (All Other Fees) of this Appendix. Payments will be made on an ‘as required’ basis and include all iCT defined Trial Site specific multipliers.
6. **Additional itemised costs**
	1. The Sponsor, or the party acting on their behalf, will reimburse any costs additional to those described in this Appendix, if properly incurred by the Trial Site in pursuance of the Clinical Trial, and supported by complete and agreed Case Report Forms, Travel Receipts, or other relevant documentation via the invoicing, approval and payment system set-up for this Clinical Trial.
7. **Payment Details**
	1. Following confirmation of invoice content, by or on behalf of the Sponsor prior to invoice generation, invoices should be sent to the following invoice address:

|  |  |
| --- | --- |
| Name:  | *[Sponsor to insert relevant details]* |
| Job title: | *[Sponsor to insert relevant details]* |
| Address: | *[Sponsor to insert relevant details]* |
| Reference on Invoice: | *[Sponsor to insert relevant details]* |
| Telephone No:  | *[Sponsor to insert relevant details]* |
| Email: | *[Sponsor to insert relevant details]* |

* 1. Invoicing queries to the Trial Site should be sent to:

|  |  |
| --- | --- |
| Name:  | *[Trial* Site *to insert relevant details]* |
| Job title: | *[Trial* Site *to insert relevant details]* |
| Address: | *[Trial* Site *to insert relevant details]* |
| Reference on Invoice: | *[Trial* Site *to insert relevant details]* |
| Telephone No:  | *[Trial* Site *to insert relevant details]* |
| Email: | *[Trial* Site *to insert relevant details]* |

* 1. Payments by the Sponsor, or the party acting on their behalf, will be made by BACS to:

|  |  |
| --- | --- |
| Bank | *[Trial* Site *to insert relevant details]* |
| Address | *[Trial* Site *to insert relevant details]* |
| Account Name | *[Trial* Site *to insert relevant details]* |
| Account No | *[Trial* Site *to insert relevant details]* |
| Sort Code | *[Trial* Site *to insert relevant details]* |
| Swift Code | *[Trial* Site *to insert relevant details]* |
| IBAN No | *[Trial* Site *to insert relevant details]* |
| VAT Code | *[Trial* Site *to insert relevant details if applicable or mark as Not Applicable]* |

1. **Finance Schedule**

[The Sponsor, or party acting on their behalf, should insert here the Finance Schedule generated from the site-level iCT relevant to this Trial Site, following completion of iCT study resource review and prior to sharing this contract with the Trial Site for contract execution. Modifications to the Finance Schedule generated by iCT are not permitted. **DELETE THIS GUIDANCE FOLLOWING INSERTION OF FINANCE SCHEDULE**]