HRA Statement of Activities

Health Research Authority

for Participating NHS Organisations in England (template version 4.1)

For non-commercial studies, one Statement of Activities should be completed as a template for each site-type in the study. Each Statement of Activities should be accompanied by a completed HRA Schedule of Events, as part of the submission via IRAS for HRA Approval.

Blue shaded fields (also marked with an asterisk) should be completed by the sponsor/applicant prior to submission to the HRA.*
Where appropriate, for the purpose of confirming capacity and capability, green shaded fields (also marked with a caret^) should be completed by the participating organisation before returning the document to the sponsor.
Other questions may be completed either by the sponsor/applicant or participating organisation (or collaboratively between both parties), as appropriate.

For participating organisations in Northern Ireland, Scotland or Wales, the sponsor should transfer a Site Specific Information Form to each local research team for completion and submission to their research management support function.

To provide an answer in the form, click in a box with the blue text and over-write this text, or select the relevant option if presented with drop-down text. A separate guidance document is provided and should be consulted prior to completion of this template. Please also read the question specific guidance where present.

IRAS ID*	219487
Short Study Title*	RAMPART
Full Study Title*	Renal Adjuvant MultiPle Arm Randomised Trial: an international investigator-led phase III multi-arm multi-stage multi-centre randomised controlled platform trial of adjuvant therapy in patient with resected primary renal cell carcinoma (RCC) at high or intermediate risk of relapse
Contact details of sponsor, or sponsor's delegated point of contact (e.g. Study Manager), for questions relating to study set-up*	Ben Smith (mrcctu.rampart@ucl.ac.uk) Francesca Schiavone (mrcctu.rampart@ucl.ac.uk) Telephone: 0207 670 4683/4743 MRC Clinical Trials Unit at UCL 90 High Holborn, 2nd floor London WC1V 6LJ
Site Type*	All Site Activities *Select one option. If 'Other', give details.* If 'Other', insert details here

Name of Participating Organisation	*Where this statement is to be used as the agreement between sponsor and participating organisation, the name of the participating organisation should be entered here prior to agreement. If this Statement is being agreed to cover multiple separate entities (e.g. multiple GP practices within a single LCRN geography) please make this clear here.* Enter name of participating organisation
Location/s within Participating Organisation	*Where the research is planned to take place only at specified hospitals or other locations within the participating organisation (as may be the case in an NHS Trust comprised of more than one hospital) please name those hospitals/locations here.* Aberdeen Royal Infirmary

	Addenbrooke's Hospital Beatson West of Scotland Cancer Centre Bristol Haematology & Oncology Centre Broomfield Hospital Castle Hill Hospital Cheltenham General Hospital Churchill Hospital Clatterbridge Cancer Centre Colchester General Hospital Derriford Hospital Diana Princess of Wales Hospital Freeman Hospital Glan Clwyd Gloucestershire Royal Hospital Good Hope Hospital Guy's Hospital Ipswich Hospital James Cook Hospital Leicester Royal Infirmary Maidstone Hospital Mount Vernon Hospital Musgrove Park Hospital Norfolk and Norwich Hospital Nottingham City Hospital Queen Alexandra Hospital Queen Elizabeth Hospital (Birmingham) Raigmore Hospital Royal Berkshire Hospital Royal Bournemouth Hospital Royal Derby Hospital Royal Devon and Exeter Hospital Royal Free Hospital Royal Marsden Hospital (Fulham) Royal Marsden Hospital (Sutton) Royal Preston Hospital Royal Stoke University Hospital Salisbury District Hospital Scunthorpe General Hospital South Tyneside District Hospital

	Southend University Hospital St Bartholomew's Hospital St James' University Hospital Sunderland Royal Hospital The Christie Torbay Hospital Velindre Cancer Centre Weston Park Hospital Ysbyty Gwynedd/Bangor Hospital

Date *HRA Office Use Only*	*Date template assessed by HRA*
Version Number *HRA Office Use Only*	Applicant version assessed by HRA

1. Does the sponsor intend that this document forms the agreement between itself and the participating organisation/s in England?*

For non-commercial studies other than clinical trials and clinical investigations, the HRA encourages use of the Statement of Activities as the only form of agreement between sponsor and an English participating organisation, in place of bespoke agreements created by sponsors. For research in primary care settings, the Statement may be used for a geographical area, e.g. at the LCRN level, although agreement should be between the sponsor and independent legal entity (e.g. GP Practice). For clinical trials and clinical investigations the HRA expects that sponsors will use the relevant model agreement, where one exists.

No

2. **Date this Statement of Activities confirmed by participating organisation, if applicable.^**

Enter date confirmed

3. Confirmation on behalf of participating organisation provided by (insert name and job title), if applicable.^

Enter name and job title

It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the sponsor and participating organisation. Instead, sponsors are expected to accept confirmation by email from an individual empowered by the participating organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).

4. If this Statement is not intended to form the agreement with the participating organisation/s in England, will the sponsor be using an unmodified model non-commercial agreement?*

Yes

5. If no, please provide details of the modifications made to the model agreement and the reasons for them. If the sponsor intends to use an agreement not based on the model agreement, please provide detailed justification for this (templates of all 'site agreements' to be used, including for sites in the devolved administrations (where applicable) should be provided as part of the submission for HRA Approval).*

6. Predicted Participant Recruitment, if applicable.

This is recruitment or identification at participating organisation, not overall for the study. Please clarify if this refers to participants, samples or data. Please clearly state if this is per month, per year, overall etc. Leave blank if not applicable to this site type.

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7. Proposed start date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the commencement of screening, the recruitment of the first participant, etc.

Research/participant identification activity: Q1-2018

This start date is defined as the day the trial team confirms site is officially open to recruitment

8. Predicted end date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the recruitment of the final participant, the final visit of the final participant, database lock, etc.

End of recruitment: 2023-2024

The date above indicates the estimated date for recruitment closure under the current design with three research arms (Arm A, B and C). When an additional arm will be launched, the recruitment date will need to be extended.

All patients will continue long-term follow-up until the primary outcome has been reached (Overall Survival). Realistic follow-up procedures will be put in place to allow sites flexibility in following the cohort up successfully. Telephone and nurse-led follow-up will be permitted and activities outlined in the protocol and supporting documents for site activities.

9. Person responsible for research activities at site.*

Local Principal Investigator

The HRA expects Principal investigators to be in place at participating organisations where locally employed staff take responsibility for research procedures. Where this is not the case, the HRA expects Local Collaborators to be in place where central study staff will be present at site to undertake research procedures (the role of the Local Collaborator is to support practical arrangements for the presence of research staff under Letters of Access or Honorary Research Contracts). Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at site, the HRA does not expect that a Principal Investigator or Local Collaborator is appointed and you should select Chief Investigator.

10. Are you requesting support to identify a Principal Investigator or Local Collaborator?*

Please indicate whether support from the host organisation is being requested to identify a Principal Investigator/Local Collaborator and provide further information on expectations below. Where a Principal Investigator or Local Collaborator has already been identified, their details appear on Part C of the IRAS Form.

No

11. Further Information (where applicable).*

Please provide further information on sponsor expectations for a Principal Investigator/Local Collaborator, to help participating organisations identify an appropriate individual if required (e.g. Profession, specialty, seniority etc.)

Most UK collaborators will be selected by the Sponsor based on ongoing collaborations with exisiting MRC CTU trials (SORCE; MRC RE05). Investigators will be approached for expression on interest and feasibility at each site assessed by the Sponsor.

We expect Principal Investigators to be clinical oncologists and urologists at consutant level. Consideration will be given on a case by case basis for local clinicians holding a locum contract with the NHS Trust.

12. The following capabilities and capacity are needed locally in order to deliver the study, e.g. specific equipment, patient/participant groups, service support nursing time, excess treatment costs, etc.*

Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule.

Long-term follow-up is essential for the success of the trial and reliability of the results. Sites are expected to ensure trial participants are followed up in clinic during their treatment phase and before disease progression, remotely if needed after disease progression and via clinical notes or GPs if the participant is no longer followed up at the site as part of routine clinical care.

The trial has been designed with regulatory futureproofing in mind to allow for a potential licence extension application to FDA and EMA should the results from Disease Free Survival and Overall Survival analyses be positive. Therefore, sites will undergo close central and on site monitoring with regular data chase and cleaning activities to ensure the trial is fit for regulatory submission.

13. Projected NHS Treatment Cost savings at this site type, if applicable.*

Although many studies incur Excess Treatment Costs (see AcoRD for information on cost attribution) many studies also give rise to treatment cost savings during the study (e.g. a two armed study comparing standard care to a less intensive, and less expensive, alternative treatment). Please describe below any projected treatment cost savings, so your participating organisations may include this information when considering the overall treatment costs/cost savings of their portfolio of research. Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule. Excess Treatment Costs will be indicated above (question 12) and in the HRA Schedule of Events.

No treatment cost savings are expected.

14. The following training for local staff will be provided by the sponsor. Where only specific team members (e.g. the Principal Investigator) will receive this training, this is described below.*

Sites will undergo extensive training at activation. This will involve a mix of in person and remote (via teleconference) training activities. A refresher training programme will be in place to ensure investigators and researchers are aware of all current trial requirements. Any subsequent amendment for the addition of new research arms or early stopping following interim analysis will be preceded by further extensive training to all participating centres.

The training package will include:

:: Overview on eligibility, treatment, follow-up and safety reporting

:: Overview on CRF completion guidelines

:: Overview of Drug Supply Management System and Image Repository systems

:: Any relevant updates on protocol changes

15. In addition to the above training, to be provided by the sponsor, the sponsor also expects that the following local research team members will undertake or have already undertaken the following training.*

It would not be usual for the sponsor to expect study specific training additional to that which it will provide, this section does however allow sponsors to state that they will accept, for example, NIHR CRN training in Good Clinical Practice where the study is a Clinical Trial of an Investigational Medicinal Product etc.

Good Clinical Practice training will be required by all research and clinical members involved in any trial activity. Training needs to be recent and current but the standards can be dictacted at local level. It is advised training is refreshed at least every 2 years but local Trust policy on GCP training can be observed.

If Research Nurses are to be involved in consenting activities, it is strongly recommended evidence of training on informed consent is provided to the Sponsor.

A current CV for all research team members is expected to be filed in the Investigator Site File (ISF) and available for monitoring, auditing and inspection. Evidence of all academic and clinical qualifications need to be filed in the ISF. Where not possible, RCP and RCN membership numbers need to be detailed on CV.

Attendance to trial-specific training will be confirmed via email or attedance certificates. All evidence of training should be kept on records.

Schedule 1 (Finance) (template version 4.1)

Please select one of the following*	
There are no funds/resources/equipment, etc. being provided to this/these organisation/s by the sponsor. *This schedule should be left blank.**	☐
The following funding/resources/equipment, etc. is to be provided to this/these local participating organisation/s. However, the finance schedule to cover such transfer is detailed in a separate agreement. *Please complete the information below but leave the schedule blank and submit your separate agreement to the HRA.**	☒
Per patient payments (PPP) will be in place for participating centres. Key Performance Indicators and milestone payments will be detailed in the CTA. PPP use will be at the discretion of the local institution, however it is suggested that they may be used to cover the following areas of activity: :: clinician and research team time for patient identification and screening, consent, randomisation and follow up :: clinician and supporting departments (Pharmacy) time for treatment administration :: research team time for data collection All Investigational Medicinal Products will be provided by the Sponsor free-of-charge Equipment for biological samples collection will be provided to sites. This will be detailed in a subsequent amendment when the translational sub-studies are activated.	
The following funding/resource/equipment, etc. is to be provided to this local participating organisation. This Statement of Activities is intended by the sponsor to form the agreement between them and the participating organisation. The finance schedule below details the funds to be provided to the site by the sponsor. *Please complete the information and the schedule below.[1]**	☐

1 Payment Schedule (i.e. frequency or trigger for payments)* Payment schedule and milestones are detailed in the Clinical Trial Agreement circulated to sites as part of the submission pack
2 Area of Cost (e.g. set-up, procedure, overall cost, etc.)* Trial conduct and recruitment

Payment Details:

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment on presentation of a VAT invoice. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

[1] The Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales

3 Invoices to be submitted to (insert job title, name of body and address)*

RAMPART Trial Manager

MRC Clinical Trials Unit at UCL

90 High Holborn, 2nd Floor

London

WC1V 6LJ

4 Payment to be made by cheque to^

Enter cheque payable details

4.1 AND remitted to (insert job title/position and address)

Enter job title/position and address

OR

5 Arrange BACS transfer to: Bank Name

Enter bank name

5.1 Sort Code

Enter sort code

5.2 Account Number

Enter account number

5.3 And send the relevant paper work to the following address

Enter address details

Invoices should be presented promptly. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding from an external funding body has been irrecoverably reclaimed by such external funding body as a result of such delay or inadequacy.

Schedule 2 (Material Transfer Provisions)

(template version 4.1)

These provisions do not remove the responsibility for a sponsor to clearly lay out in their protocol (and to potential participants in the patient information sheet/s) at a minimum the following information for all human biological material taken: 1) The nature of the materials, 2) The reason that the material is being taken, 3) where the material is to be sent, 4) what will happen to any remaining material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction).

Detailed guidance on what information should be included in a protocol may be found on the HRA website http://www.hra.nhs.uk

Please select one of the following*	
This study does not involve the transfer of human biological material from this participating organisation to the sponsor or its agents. ***This schedule does not form part of this agreement.****	☐
The Sponsor has separately provided to the HRA and participating organisation an agreement for the transfer of human biological material. ***This schedule does not form part of this agreement.****	☒
These provisions form part of the agreement between the sponsor and this participating organisation. ***Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.**[2]	☐

1 Where the protocol requires the participating organisation to supply material to the sponsor/joint sponsor(s)/either of the co-sponsors, these provisions shall apply if stated above.

2 In accordance with the protocol, the participating organisation shall send material to the sponsor/joint sponsor(s)/a co-sponsor or, in accordance with provision 8 below, a third party nominated by the sponsor/joint sponsor(s)/either of the co-sponsors.

3 The participating organisation warrants that all material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006[3] (as the case may be)) and as required by the protocol.

4 Subject to provision 3 above, the materials are supplied without any warranty, expressed or implied including as to their properties, merchantable quality, fitness for any particular purpose, or that the materials are free of extraneous or biologically active contaminants which may be present in the Materials.

5 The sponsor/joint sponsor(s)/one of the co-sponsors shall ensure, or procure through an agreement with the sponsor/joint sponsor(s)/co-sponsors nominee as stated in provision 2 above that.

5.1 the material is used in accordance with the protocol, the consent of the participant, and the HRA Approval for the Study,

5.2 the material is handled and stored in accordance with applicable law,

[2] The HRA Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales.

[3] Although the HRA Statement of Activities is not intended for use with participating organisations in Scotland, studies taking place in England might involve transfer of Human Tissue to Scotland for (for example) analysis in a central technical facility.

5.3 the material shall not be redistributed or released to any person other than in accordance with the protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the participant's consent, and

5.4 no alteration shall be made to the title, coding or acronym of the material.

6 The parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.

7 The participating organisation and the sponsor/joint sponsors(s)/a co-sponsor shall each be responsible for keeping a record of the material that has been transferred according to these provisions.

8 To the extent permitted by law the participating organisation and its staff shall not be liable for any consequences of the supply to or the use by the sponsor/joint sponsors//co-sponsor of the material or of the supply to or the use by any third party to whom the sponsor/joint sponsors/co-sponsor subsequently provides the material or the Sponsor's/Joint Sponsors/Co-Sponsor's nominee as stated in provision 2 above, save to the extent that any liability which arises is a result of the negligence of the participating organisation.

9 The sponsor/joint sponsors/co-sponsor undertake(s) that, in the even that material is provided to a third party in accordance with provision 2 above, it/they shall require that such third party shall undertake to handle any data and Material related to the Study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in these provisions.

10 Any surplus material that is not returned to the participating organisation or retained for future research (in line with participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004).

Schedule 3 (Confidentiality, Data Protection and Freedom of Information) (template version 4.1)

Please select one of the following*	
This study does not involve the transfer of Personal Data from this participating organisation to the sponsor or its agents, nor is there transfer of confidential information between the parties. ***This schedule does not form part of this agreement.****	☐
The Sponsor has separately provided to the HRA and participating organisation another agreement for the transfer of data. ***This schedule does not form part of this agreement.****	☒
These provisions form part of the agreement between the sponsor and this participating organisation. ***Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.**[4]	☐

1. Participant Confidentiality
   1.1. The parties agree to adhere to all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants
   1.2. Personal Data shall not be disclosed to the sponsor by the participating organisation, save where this is required directly or indirectly to satisfy the requirements of the Protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a participant in connection with the study.
   1.3. Neither the sponsor nor the participating organisation shall disclose the identity of participants to third parties without the prior written consent of the participant except in accordance with applicable statutory requirements and codes of practice, including HSCIC Code of Practice on Confidential Information.
   1.4. The sponsor agrees to act as Data Controller in relation to any processing of Personal Data under this agreement. This extends to all processing that would not have taken place but for this agreement regardless where that processing takes places. In particular, it extends to processing by the participating organisation where that processing is undertaken solely for the purposes of the study.
   1.5. The sponsor agrees to comply with the obligations placed on a Data Controller by the Data Protection Act 1998. This is not limited to, but includes, ensuring that:
      1.5.1. Personal Data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes
      1.5.2. Personal Data are adequate, relevant and not excessive in relation to the purpose or purposes described within the protocol.
      1.5.3. Personal Data shall be accurate and, where necessary, kept up to date.
      1.5.4. Personal Data shall be processed in accordance with the rights of data subjects under the Data Protection Act 1998.
   1.6. The Sponsor agrees to ensure appropriate training. In particular:
      1.6.1. To ensure that any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating Site) processing

[4] The HRA Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales.

Personal Data are subject to annual mandatory training in the information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data;

1.6.2. To ensure that the Senior Information Risk Owners, e.g. Caldicott Guardians, senior partners and board members of the sponsor (or organisational equivalent of each of these) complete additional data security training annually.

1.7. The participating organisation agrees to ensure that its employees, honorary employees, students, researchers, consultants and subcontractors processing Personal Data are subject to annual mandatory training in the information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data;

1.8. The sponsor agrees to use Personal Data solely in connection with the operation of this agreement and the study and not otherwise. In particular;

1.8.1. Not to disclose Personal Data in whole or in part to any person without the participating organisation's prior written consent;

1.8.2. Not to disclose other than pursuant to a data sharing agreement that conforms to the requirements set out in the Information Commissioner's data sharing code of practice.

1.9. The participating organisation agrees to act as Data Processor on behalf of the sponsor as Data Controller for processing undertaken under this agreement solely for the purposes of the study. The participating organisation agrees to comply with the obligations placed on it as the data controller by the seventh data protection principle ("the Seventh Principle") set out in the Data Protection Act 1998, namely:

1.9.3. to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on the Data Controller by the Seventh Principle;

1.9.4. only to process Personal Data for and on behalf of the Data Controller, in accordance with the instructions of the Data Controller and for the purpose of the study and to ensure the Data Controller's compliance with the Data Protection Act 1998;

1.9.5. to allow the sponsor to audit the participating organisation's compliance with the requirements of this clause on reasonable notice and/or to provide the Data Controller with evidence of its compliance with the obligations set out in this clause;

1.9.6. the participating organisation shall obtain prior agreement of the sponsor to store or process Personal Data at sites outside the European Economic Area (comprising the countries of the European Community, Norway, Iceland and Liechtenstein).

2. Freedom of Information

2.1. Parties to this agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another party shall notify and consult that party, as soon as reasonably practicable, and in any event, not later than seven (7) calendar days after receiving the request.

2.2. The parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the party responding to the request.

2.3. Where the party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other party in writing, giving at least four (4) calendar days' notice of its intended disclosure.

3. Confidential information

3.1. The receiving party agrees to take all reasonable steps to protect the confidentiality of the confidential information and to prevent it from being disclosed otherwise than in accordance with this agreement.

3.2. Subject to clause 3.4 below, the participating organisation agrees to treat the results, excluding any clinical data of the study, as confidential information disclosed by the sponsor and the sponsor agrees to treat Personal Data as confidential information disclosed by the participating organisation.

3.3. The receiving party agrees:

- 3.3.1. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the study are made aware of, and abide by, the requirement of this clause 3 and, where relevant, clause 2.
- 3.3.2. To use confidential information solely in connection with the operation of the agreement and not otherwise.
- 3.3.3. Not to disclose confidential information in whole or in part to any person without the disclosing party's prior written consent.

3.4. The provision of clause 3 shall not apply to the whole or any part of the confidential information that is:

- 3.4.1. lawfully obtained by the receiving party free of any duty of confidentiality;
- 3.4.2. already in the possession of the receiving party and which the receiving party can show from written records was already in its possession (other than as a result of a breach of clause 3.1 or 3.2);
- 3.4.3. in the public domain (other than as a result of a breach of clause 3.1 or 3.2);
- 3.4.4. independently discovered by employees of the receiving party without access to or use of confidential information;
- 3.4.5. necessarily disclosed by the receiving party pursuant to a statutory obligation;
- 3.4.6. disclosed with prior written consent of the disclosing party;
- 3.4.7. necessarily disclosed by the receiving party by virtue of its status as a public authority in terms of the Freedom of Information Act 2000;
- 3.4.8. published in accordance with HRA expectations on research transparency.

3.5. The restrictions contained in clauses 2 and 3 shall remain in force without limit in time in respect of Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

Appendix 1 (Staff signature and delegation log) (template version 4.1)

This Appendix is for use at the discretion of the sponsor and participating organisation, to record the roles and responsibilities of the local research team (where applicable) and the authorisation of the Principal Investigator (PI) for this.

Please select one of the following*	
The sponsor intends to use this template as the delegation log for this participating organisation	☐
The sponsor intends to use a delegation log based on another template for this participating organisation	☒
The sponsor is not proposing that a delegation log is completed for this participating organisation	☐

IRAS ID	**Name of Participating Organisation**
Enter IRAS ID	Enter name of participating organisation

Name of Principal Investigator	**PI's Signature**[1]	**PI's Initials**	**Start** (dd/mmm/yy)	**End** (dd/mmm/yy)
Enter name			Enter start date	Enter date

[1]My signature confirms/acknowledges that the information contained in this delegation log is accurate and that:

a. I will conduct the study in accordance with the protocol and remain responsible for the overall study conduct at the participating organisation and for the reported data.
b. I will ensure study oversight.
c. I will authorise the delegation of study-related tasks to each individual as listed.
d. The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.
e. I will ensure that all personnel assisting in the conduct of the study are informed about their obligations and will not have performed any delegated study-related tasks prior to appropriate delegation and completion of study training appropriate to the role.
f. I will ensure that participating organisation staff receive, in a timely manner, the appropriate information and training.
g. I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
h. Neither I, nor any dependents, have entered into and will not enter into arrangements, financial or otherwise, with any third party providing support, products and/or services to the study that would present a conflict of interests
i. I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner.
j. I consent to the sponsor, and to any relevant third party providing support, products and/or services to the Study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

Study Task Key:

The sponsor may detail in the below key the main study activities that the PI can delegate to staff at the participating organisation. The task list and delegation log are intended to be maintained as an up to date document throughout the duration of the study at the participating organisation.

1. Screens/recruits study subjects	6. Enter other task here	11. Enter other task here	16. Enter other task here
2. Obtains Informed Consent	7. Enter other task here	12. Enter other task here	17. Enter other task here
3. Confirms eligibility (Inclusion/Exclusion)	8. Enter other task here	13. Enter other task here	18. Enter other task here
4. Enter other task here	9. Enter other task here	14. Enter other task here	19. Enter other task here
5. Enter other task here	10. Enter other task here	15. Enter other task here	20. Enter other task here

Name	**Signature[2]**	**Initials**	**Study Role**	**Study Task(s) (Select from key)**	**Start of task(s)** (dd/mmm/yy)	**PI Initials**	**End of task(s)** (dd/mmm/yy)	**PI Initials**

[2]My signature confirms/acknowledges that I accept the assigned study task/s and that:

- I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority, and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
- I consent to the sponsor, and to any relevant third party providing support, products and/or services to the study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

I confirm that the information contained in this delegation log is accurate and complete. (To be completed by the PI at the end of the study).

PI name: Signature: Date:

User Feedback (template version 4.1)

Please complete this form with your comments on the usability of the Statement of Activities and return by email to: hra.approvalprogramme@nhs.net

Comments

Enter comments here

What we will do with your response?

The HRA has a commitment to transparency. We will analyse the comments we receive, and publish a report on our website explaining how we will address the themes raised. The published report will compare the views of different organisations and groups of individuals.

Organisational responses: In the interest of transparency, all comments made on behalf of an organisation will normally be published and attributed unless an explanation is provided with your response as to why you consider the information should not be. (Please note the Confidentiality of Information section below.)

Individual responses:

Comments will be summarised in a way that does not identify individual respondents unless we have your permission to identify you.

Are you responding in an organisation or personal capacity?

Organisation Capacity	☐
Personal Capacity	☐

If you are replying in an organisational capacity, please note that your response may be published and quoted in the final report.

Organisational responses only

If you do not wish your organisational response, and any quotes used from it, to be identified in any consultation report and any future HRA publications, or published once the consultation has ended.

Please provide explanation of why you do not wish us to publish your organisational response

Individual responses only

I am responding primarily as a: (please check only one box):

Research Team Member	☐	NHS Staff	☐
Member of the public	☐	Industry	☐
REC Member	☐	Phase 1 Company	☐
REC Staff	☐	Regulatory Body	☐
R&D Community	☐	Academic	☐
Other (Please specify)	☐		

Please specify if answered 'Other'

I am willing for my response, and quotes used from it, to be used in non-identifiable form in any consultation report and any future HRA publications:

I am willing for my response, and quotes used from it, to be made identifiable in any consultation report and any future HRA publications:

Select 'yes' or 'no'

All responses

I am willing to be contacted by the HRA for further information in relation to this consultation or future consultations.

Select 'yes' or 'no'

If ‘yes’, please provide your contact details below. By providing these contact details, you are giving your consent for a member of HRA staff to contact you about your submission. The HRA takes data protection very seriously. We promise we will not pass your details on to any other organisations or use them for any other purposes.

Contact Name:

Enter contact name

Email:

Enter email address

Confidentiality of Information

The HRA will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties without your permission or unless required by law. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the HRA.