HRA and HCRW

Statement of Activities for participating NHS organisations in England or Wales

(Template version 4.4)

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 Health Research Authority (HRA) and Health and Care Research Wales (HCRW) Schedule of Events, as part of the submission via IRAS for HRA and HCRW Approval.

Blue shaded fields (also marked with an asterisk*) should be completed by the sponsor/applicant prior to submission to HRA and HCRW.
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 or Scotland, 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 withdrop-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*	255698
Short study title*	The Gentle Years Yoga Trial
Full study title*	Individually randomised controlled multi-centre trial to determine the clinical and cost-effectiveness of an adapted yoga programme for older adults with multimorbidity, including an embedded process evaluation
Contact details of sponsor, or sponsor's delegated point of contact (e.g. Study Manager), for questions relating to study set-up*	[redacted]
Site Type*	Participant Identification Centre 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, please enter the name of the participating organisation here prior to agreement. If this Statement is being agreed to cover multiple separate entities (e.g. in England, multiple GP practices within a single LCRN region) please make this clear here. This Statement is being agreed to cover multiple GP practices within a single LCRN region
Location/s within Participating Organisation	Where it is planned to undertake the research only at specified hospitals or other locations within the participating organisation (as may be the case in an NHS Trust / Health Board comprised of more than one hospital) please name those hospitals/locations here. Enter name/s of locations within participating organisation

Date HRA and HCRW office use only	Date template assessed by HRA and HCRW
Version Number HRA office use only	Applicant version assessed by HRA and HCRW

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

For non-commercial studies other than clinical trials and clinical investigations, HRA and HCRW encourage use of the Statement of Activities as the only form of agreement between sponsor and an English or Welsh participating organisation, in place of bespoke agreements created by sponsors. For research in primary care settings in England, 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 and HCRW expect that sponsors will use the model agreement for non-commercial research (mNCA).

Yes

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 <u>NOT</u> intended to form the agreement with the participating organisation/s in England and / or Wales, will the sponsor be using an unmodified model non-commercial agreement (mNCA)?***

Select 'yes' or 'no'

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 each UK nation (where applicable) should be provided as part of the submission for HRA and HCRW Approval).***

Provide details of modification made to model agreement and the reasons for them.

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. Please state if not applicable to this site type.

Overall, we aim to recruit 586 participants from 12 'sites'. Therefore, each 'site' will aim to 49 participants on average. Each 'site' will comprise approximately 3 GP practices.

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

Applicants may choose to leave the date field blank, for negotiation with individual sites, where there is significant uncertainty as to exact dates at the time of application for HRA and HCRW Approval.

01/Jul/2019

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.

Start of Recruitment

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

Applicants may choose to leave the date field blank, for negotiation with individual sites, where there is significant uncertainty as to exact dates at the time of application for HRA and HCRW Approval.

30/Jun/2021

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

9. Person responsible for research activities at site.*

Chief Investigator (Central Study Team)

- The HRA and HCRW expect principal investigators to be in place at participating organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single site studies where the Chief Investigator will also be the Principal Investigator.
- Where this is not the case, the HRA and HCRW expect 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, Honorary Research Contracts or similar arrangements).
- 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 and HCRW do 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 participating 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.)

N/A

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.

1. Capable and willing to carry out a database search to identify potential participants - need to establish which systems work with the codes
2. Willing to post recruitment packs out to these identified participants
3. GP willing to respond to letters from York Trials Unit confirming participant eligibility when needed

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 and HCRW Schedule of Events.

None

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.*

No training provided as the sites are acting as PICs

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.

None

Schedule 1 – Finance
(Template version 4.4)

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 and HCRW.*	☐
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]	☒
Please refer to costs detailed in the primary care research costing template.	

1 Payment Schedule (i.e. frequency or trigger for payments)* The end of a recruitment wave will be the trigger for first payment. If any adverse event information is provided, payment will be made at the end of follow (approx 12 months after recruitment).
2 Area of Cost (e.g. set-up, procedure, overall cost, etc.)* Research costs as detailed in the primary care research costing template

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 or Scotland

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

[redacted]

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 4.4)

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.

Please select one of the following*	
This study does not involve the transfer of human biological material (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 HCRW 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 or to a third party nominated by the sponsor, and where indicated above, this Schedule 2 shall apply.
2. In accordance with the protocol, the participating organisation shall send Material to the sponsor or, in accordance with provision 8 below, to a third party nominated by the sponsor.
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 (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.

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

5. The sponsor shall ensure, or procure through an agreement with the sponsor's 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 ethics approval for the study;

    5.2 the Material is handled and stored in accordance with applicable law;

    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 shall each be responsible for keeping a record of the Material that has been transferred according to this Schedule 2.

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 of the Material or of the supply to or the use by any third party to whom the sponsor subsequently provides the Material or the 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 undertakes that, in the event that Material is provided to a third party in accordance with provision 2 above, it shall require that such third party shall undertake to handle any 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 this Schedule 2.

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 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

Schedule 3 – Data processing
(Template version 4.4)

Please select one of the following*	
This study does not involve any processing of personal data by this participating organisation on behalf of the sponsor. This schedule does not form part of this agreement.*	☐
The sponsor has separately provided to the HRA and HCRW (and will provide to the participating site/s) another GDPR Article 28 compliant agreement (e.g. mNCA) for the processing of personal data by the participating organisation. 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 the site will be processing data on behalf of the sponsor, no other agreement is provided, and the terms below therefore constitute the data processing agreement for this study (for the avoidance of doubt, when used, these provisions are intended to form a legally binding contractual obligation for the purposes of compliance with the GDPR, specifically GDPR Article 28 (3))*[3]	☒

1. The parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including, where applicable, medical confidentiality) in relation to participants.
2. For the purposes of the General Data Protection Regulation (GDPR) and Data Protection Act 2018 (the Data Protection Legislation), the sponsor is the controller and the participating organisation is the sponsor's processor in relation to all processing of personal data (as defined in the Data Protection Legislation) that is processed by the participating organisation for the purpose of this study and for any future research use under the controllership of the sponsor, that would not have taken place but for this agreement regardless where that processing takes place.
3. The parties acknowledge that whereas the sponsor is the controller in accordance with clause 2, the participating organisation is the controller of the personal data collected for the purpose of providing clinical care to the participants (or other purposes, as applicable). This personal data may be the same personal data, collected transparently and processed for research and for care (or other) purposes under the separate controllerships of the sponsor and participating organisation.

[3] The HRA and HCRW Statement of Activities is not intended for use with participating organisations in Northern Ireland or Scotland.

4. Where the participating organisation is the sponsor's processor and thus where the processing is undertaken by the participating organisation for the purposes of the study, clauses 6.7 to 6.16 below will apply. For the avoidance of doubt, such clauses do not apply where the participating organisation is processing the participant personal data as a controller.
5. The participating organisation agrees only to process personal data for and on behalf of the sponsor in accordance with the instructions of the sponsor and for the purpose of the study and thereby to ensure the sponsor's compliance with the Data Protection Legislation;
6. The participating organisation agrees to comply with the obligations applicable to processors described by Article 28 of the GDPR including, but not limited to, the following:

    6.7. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the controller by Article 28(1);

    6.8. to not engage another processor without the prior written authorisation of the sponsor (Article 28(2));

    6.9. to process the personal data only on documented instructions from the sponsor unless required to do otherwise by legislation, in which case the participating organisation shall notify the sponsor before processing, or as soon as possible after processing if legislation requires that the processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a));

    6.10. to ensure that personnel authorised to process personal data are under confidentiality obligations (Article 28(3b));

    6.11. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));

    6.12. to respect the conditions described in Article 28(2) and (4) for engaging another processor (Article 28(3d));

    6.13. to, taking into account the nature of the processing, assist the sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising data subjects' rights (Article 28(3e));

    6.14. to assist the controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the processing and the information available to the participating organisation (Article 28(3f));

    6.15. to, at the choice of the sponsor, destroy or return all personal data to the sponsor at the end of the study at the participating organisation, unless storage is legally required (Article 28(3g)) or where that personal data is held by the participating organisation as controller for the purpose of clinical care or other legal purposes; and

    6.16. to maintain a record of processing activities as required by Article 30(2) GDPR.

7. The participating organisation shall ensure that:
    7.7. its agents do not process personal data except in accordance with this agreement (and the protocol);
    7.8. it takes all reasonable steps to ensure the reliability and integrity of any of its agents who have access to the personal data and ensure they:
        7.8.1. are aware and comply with the participating organisation's duties under this agreement;
        7.8.2. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and
        7.8.3. are informed of the confidential nature of the personal data and understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.
8. The participating organisation agrees to:
    8.7. allow the sponsor(s) or another auditor appointed by the sponsor(s) to audit the participating organisation’s compliance with the obligations described by this agreement, Data Protection Legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the sponsor complying with all relevant health and safety and security policies of the participating organisation and/or to provide the sponsor with evidence of its compliance with the obligations set out in this agreement; and
    8.8. obtain prior agreement of the sponsor to store or otherwise process personal data outside the European Economic Area.
9. Where the participating organisation stores or otherwise processes personal data outside of the European Economic Area as the sponsor’s processor, it warrants that it does so in compliance with the Data Protection Legislation.

Schedule 4 – Data sharing
(Template version 4.4)

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 HCRW and participating organisation another agreement for the transfer of data (e.g. mNCA). 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]	☒

Data sharing

1. 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.
2. The sponsor agrees to use personal data solely in connection with the operation of this research study, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,
    2.1. Not to disclose personal data to any person except in accordance with applicable legal requirements and codes of practice.
3. The sponsor agrees to comply with the obligations placed on a controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to processing of personal data (Article 5 GDPR)
4. The sponsor agrees to ensure persons processing personal data under this Agreement are equipped to do so respectfully and safely. In particular:
    4.1. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the participating organisation) processing personal data understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.
    4.2. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the

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

participating organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.

5. The sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular,
    5.1. To ensure that personal data are only accessible to persons who need it for the purposes of the study and to remove access as soon as reasonably possible once it is no longer needed.
    5.2. To ensure all access to personal data on IT systems processed for study purposes can be attributed to individuals.
    5.3. To review processes to identify and improve processes which have caused breaches or near misses, or which force persons processing personal data to use workarounds which compromise data security.
    5.4. To adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
    5.5. To take action immediately following a data breach or near miss.

6. The sponsor agrees to ensure data are processed using secure and up to date technology. In particular,
    6.1. To ensure no unsupported operating systems, software or internet browsers are used to support the processing of personal data for the purposes of the study.
    6.2. To put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as cyber essentials.
    6.3. To ensure IT suppliers are held accountable via contracts for protecting personal data they process and for meetings all relevant information governance requirements.

Freedom of information

7. 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 in accordance with clause 13, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.
8. 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.
9. 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) working days' notice of its intended disclosure.

Confidentiality

10. The participating organisation agrees to treat the Results, excluding any clinical data of the study, as confidential information of the sponsor and the sponsor agrees to treat personal data and confidential patient information as Confidential Information.

11. The receiving party agrees:
    - 11.1. 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
    - 11.2. 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 11.
    - 11.3. To use confidential information solely in connection with the operation of the Agreement and not otherwise, except in the case where the confidential information is personal data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
    - 11.4. Not to disclose confidential information in whole or in part to any person without the disclosing party's prior written consent or, where the confidential information is personal data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
12. The provision of clause 11 shall not apply to the whole or any part of the confidential information that is:
    - 12.1. lawfully obtained by the receiving party free of any duty of confidentiality;
    - 12.2. 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 11.1 or 11.2);
    - 12.3. in the public domain (other than as a result of a breach of clause 11.1 or 11.2);
    - 12.4. independently discovered by employees of the receiving party without access to or use of confidential information;
    - 12.5. necessarily disclosed by the receiving party pursuant to a statutory obligation;
    - 12.6. disclosed with prior written consent of the disclosing party;
    - 12.7. necessarily disclosed by the receiving party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A;

13. The restrictions contained in this schedule 4 shall remain in force without limit in time in respect of personal data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly agreed between the parties, these clauses shall remain in force for a period of 10 years after the end of the study at the participating organisation.

Appendix 1 – staff signature and delegation log

(Template version 4.4)

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. Provides information on adverse events where necessary	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:

1. 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.
2. 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 4.4)

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 may publish reports on our website explaining how we will address the themes raised. Any published reports 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 in any publication 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 any report.

Organisational responses only

If you do not wish your organisational response, and any quotes used from it, to be identified in any report or publications,

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

Individual responses only

I am responding primarily as: (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 report or publication relating to this document:

I am willing for my response, and quotes used from it, to be made identifiable in any report or publication relating to this document:

Select 'yes' or 'no'

All responses

I am willing to be contacted by the HRA for further information in relation to my comments.
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 or HCRW staff to contact you about your submission. The HRA and HCRW take 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 General Data Protection Regulation and the Data Protection Act 2018 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 2018 (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 or HCRW.

HRA and HCRW

Statement of Activities for participating NHS organisations in England or Wales

(Template version 4.4)

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 Health Research Authority (HRA) and Health and Care Research Wales (HCRW) Schedule of Events, as part of the submission via IRAS for HRA and HCRW Approval.

Blue shaded fields (also marked with an asterisk*) should be completed by the sponsor/applicant prior to submission to HRA and HCRW.
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 or Scotland, 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 withdrop-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*	255698
Short study title*	The Gentle Years Yoga Trial
Full study title*	Individually randomised controlled multi-centre trial to determine the clinical and cost-effectiveness of an adapted yoga programme for older adults with multimorbidity, including an embedded process evaluation
Contact details of sponsor, or sponsor's delegated point of contact (e.g. Study Manager), for questions relating to study set-up*	[redacted]
Site Type*	Other Select one option. If 'Other', give details. Research site

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

Date HRA and HCRW office use only	Date template assessed by HRA and HCRW
Version Number HRA office use only	Applicant version assessed by HRA and HCRW

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

For non-commercial studies other than clinical trials and clinical investigations, HRA and HCRW encourage use of the Statement of Activities as the only form of agreement between sponsor and an English or Welsh participating organisation, in place of bespoke agreements created by sponsors. For research in primary care settings in England, 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 and HCRW expect that sponsors will use the model agreement for non-commercial research (mNCA).

Yes

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 <u>NOT</u> intended to form the agreement with the participating organisation/s in England and / or Wales, will the sponsor be using an unmodified model non-commercial agreement (mNCA)?***

Select 'yes' or 'no'

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 each UK nation (where applicable) should be provided as part of the submission for HRA and HCRW Approval).***

Provide details of modification made to model agreement and the reasons for them.

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. Please state if not applicable to this site type.

Overall, we aim to recruit 586 participants from 12 'sites'. Therefore, each 'site' will aim to 49 participants on average. Each 'site' will comprise approximately 3 GP practices.

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

Applicants may choose to leave the date field blank, for negotiation with individual sites, where there is significant uncertainty as to exact dates at the time of application for HRA and HCRW Approval.

01/Jul/2019

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.

Start of Recruitment

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

Applicants may choose to leave the date field blank, for negotiation with individual sites, where there is significant uncertainty as to exact dates at the time of application for HRA and HCRW Approval.

30/Jun/2021

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

9. Person responsible for research activities at site.*

Chief Investigator (Central Study Team)

- The HRA and HCRW expect principal investigators to be in place at participating organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single site studies where the Chief Investigator will also be the Principal Investigator.
- Where this is not the case, the HRA and HCRW expect 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, Honorary Research Contracts or similar arrangements).
- 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 and HCRW do 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 participating 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.)

N/A

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.

1. Capable and willing to carry out a database search to identify potential participants - need to establish which systems work with the codes
2. Willing to post recruitment packs out to these identified participants
3. GP willing to respond to letters from York Trials Unit confirming participant eligibility when needed
4. Willing to provide data on adverse events where York Trials Unit is unable to contact the participant.
5. Search of database to provide prescrption data for the previous 3 months at baseline and the previous 12 months at 12 month follow-up. Or, provide prescription data for the previous 15 months at 12 month follow-up.

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 and HCRW Schedule of Events.

None

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.*

No training required as the sites will be identifying patients using READ codes and providing prescription data.

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.

None

Schedule 1 – Finance

(Template version 4.4)

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 and HCRW.*	☐
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]	☒
Please refer to costs detailed in the primary care research costing template.	

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

1 Payment Schedule (i.e. frequency or trigger for payments)*
The end of a recruitment wave will be the trigger for first payment. Payment for 12 month follow-up prescription data and any adverse event information that is provided, will be made at the end of follow (approx 12 months after recruitment).

2 Area of Cost (e.g. set-up, procedure, overall cost, etc.)*
Research costs as detailed in the primary care research costing template

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.

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

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 4.4)

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.

Please select one of the following*	
This study does not involve the transfer of human biological material (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 HCRW 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 or to a third party nominated by the sponsor, and where indicated above, this Schedule 2 shall apply.
2. In accordance with the protocol, the participating organisation shall send Material to the sponsor or, in accordance with provision 8 below, to a third party nominated by the sponsor.
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 (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.

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

5. The sponsor shall ensure, or procure through an agreement with the sponsor's 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 ethics approval for the study;

    5.2 the Material is handled and stored in accordance with applicable law;

    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 shall each be responsible for keeping a record of the Material that has been transferred according to this Schedule 2.

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 of the Material or of the supply to or the use by any third party to whom the sponsor subsequently provides the Material or the 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 undertakes that, in the event that Material is provided to a third party in accordance with provision 2 above, it shall require that such third party shall undertake to handle any 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 this Schedule 2.

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 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

Schedule 3 – Data processing
(Template version 4.4)

Please select one of the following*	
This study does not involve any processing of personal data by this participating organisation on behalf of the sponsor. This schedule does not form part of this agreement.*	☐
The sponsor has separately provided to the HRA and HCRW (and will provide to the participating site/s) another GDPR Article 28 compliant agreement (e.g. mNCA) for the processing of personal data by the participating organisation. 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 the site will be processing data on behalf of the sponsor, no other agreement is provided, and the terms below therefore constitute the data processing agreement for this study (for the avoidance of doubt, when used, these provisions are intended to form a legally binding contractual obligation for the purposes of compliance with the GDPR, specifically GDPR Article 28 (3))*[3]	☒

1. The parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including, where applicable, medical confidentiality) in relation to participants.
2. For the purposes of the General Data Protection Regulation (GDPR) and Data Protection Act 2018 (the Data Protection Legislation), the sponsor is the controller and the participating organisation is the sponsor's processor in relation to all processing of personal data (as defined in the Data Protection Legislation) that is processed by the participating organisation for the purpose of this study and for any future research use under the controllership of the sponsor, that would not have taken place but for this agreement regardless where that processing takes place.
3. The parties acknowledge that whereas the sponsor is the controller in accordance with clause 2, the participating organisation is the controller of the personal data collected for the purpose of providing clinical care to the participants (or other purposes, as applicable). This personal data may be the same personal data, collected transparently and processed for research and for care (or other) purposes under the separate controllerships of the sponsor and participating organisation.

[3] The HRA and HCRW Statement of Activities is not intended for use with participating organisations in Northern Ireland or Scotland.

4. Where the participating organisation is the sponsor's processor and thus where the processing is undertaken by the participating organisation for the purposes of the study, clauses 6.7 to 6.16 below will apply. For the avoidance of doubt, such clauses do not apply where the participating organisation is processing the participant personal data as a controller.
5. The participating organisation agrees only to process personal data for and on behalf of the sponsor in accordance with the instructions of the sponsor and for the purpose of the study and thereby to ensure the sponsor's compliance with the Data Protection Legislation;
6. The participating organisation agrees to comply with the obligations applicable to processors described by Article 28 of the GDPR including, but not limited to, the following:

    6.7. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the controller by Article 28(1);

    6.8. to not engage another processor without the prior written authorisation of the sponsor (Article 28(2));

    6.9. to process the personal data only on documented instructions from the sponsor unless required to do otherwise by legislation, in which case the participating organisation shall notify the sponsor before processing, or as soon as possible after processing if legislation requires that the processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a));

    6.10. to ensure that personnel authorised to process personal data are under confidentiality obligations (Article 28(3b));

    6.11. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));

    6.12. to respect the conditions described in Article 28(2) and (4) for engaging another processor (Article 28(3d));

    6.13. to, taking into account the nature of the processing, assist the sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising data subjects' rights (Article 28(3e));

    6.14. to assist the controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the processing and the information available to the participating organisation (Article 28(3f));

    6.15. to, at the choice of the sponsor, destroy or return all personal data to the sponsor at the end of the study at the participating organisation, unless storage is legally required (Article 28(3g)) or where that personal data is held by the participating organisation as controller for the purpose of clinical care or other legal purposes; and

    6.16. to maintain a record of processing activities as required by Article 30(2) GDPR.

7. The participating organisation shall ensure that:

    7.7. its agents do not process personal data except in accordance with this agreement (and the protocol);

    7.8. it takes all reasonable steps to ensure the reliability and integrity of any of its agents who have access to the personal data and ensure they:

        7.8.1. are aware and comply with the participating organisation's duties under this agreement;

        7.8.2. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and

        7.8.3. are informed of the confidential nature of the personal data and understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.

8. The participating organisation agrees to:

    8.7. allow the sponsor(s) or another auditor appointed by the sponsor(s) to audit the participating organisation’s compliance with the obligations described by this agreement, Data Protection Legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the sponsor complying with all relevant health and safety and security policies of the participating organisation and/or to provide the sponsor with evidence of its compliance with the obligations set out in this agreement; and

    8.8. obtain prior agreement of the sponsor to store or otherwise process personal data outside the European Economic Area.

9. Where the participating organisation stores or otherwise processes personal data outside of the European Economic Area as the sponsor’s processor, it warrants that it does so in compliance with the Data Protection Legislation.

Schedule 4 – Data sharing
(Template version 4.4)

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 HCRW and participating organisation another agreement for the transfer of data (e.g. mNCA). 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]	☒

Data sharing

1. 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.
2. The sponsor agrees to use personal data solely in connection with the operation of this research study, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,
    2.1. Not to disclose personal data to any person except in accordance with applicable legal requirements and codes of practice.
3. The sponsor agrees to comply with the obligations placed on a controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to processing of personal data (Article 5 GDPR)
4. The sponsor agrees to ensure persons processing personal data under this Agreement are equipped to do so respectfully and safely. In particular:
    4.1. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the participating organisation) processing personal data understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.
    4.2. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the

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

participating organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.

5. The sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular,
    5.1. To ensure that personal data are only accessible to persons who need it for the purposes of the study and to remove access as soon as reasonably possible once it is no longer needed.
    5.2. To ensure all access to personal data on IT systems processed for study purposes can be attributed to individuals.
    5.3. To review processes to identify and improve processes which have caused breaches or near misses, or which force persons processing personal data to use workarounds which compromise data security.
    5.4. To adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
    5.5. To take action immediately following a data breach or near miss.

6. The sponsor agrees to ensure data are processed using secure and up to date technology. In particular,
    6.1. To ensure no unsupported operating systems, software or internet browsers are used to support the processing of personal data for the purposes of the study.
    6.2. To put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as cyber essentials.
    6.3. To ensure IT suppliers are held accountable via contracts for protecting personal data they process and for meetings all relevant information governance requirements.

Freedom of information

7. 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 in accordance with clause 13, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.
8. 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.
9. 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) working days' notice of its intended disclosure.

Confidentiality

10. The participating organisation agrees to treat the Results, excluding any clinical data of the study, as confidential information of the sponsor and the sponsor agrees to treat personal data and confidential patient information as Confidential Information.

11. The receiving party agrees:
    - 11.1. 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
    - 11.2. 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 11.
    - 11.3. To use confidential information solely in connection with the operation of the Agreement and not otherwise, except in the case where the confidential information is personal data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
    - 11.4. Not to disclose confidential information in whole or in part to any person without the disclosing party's prior written consent or, where the confidential information is personal data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
12. The provision of clause 11 shall not apply to the whole or any part of the confidential information that is:
    - 12.1. lawfully obtained by the receiving party free of any duty of confidentiality;
    - 12.2. 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 11.1 or 11.2);
    - 12.3. in the public domain (other than as a result of a breach of clause 11.1 or 11.2);
    - 12.4. independently discovered by employees of the receiving party without access to or use of confidential information;
    - 12.5. necessarily disclosed by the receiving party pursuant to a statutory obligation;
    - 12.6. disclosed with prior written consent of the disclosing party;
    - 12.7. necessarily disclosed by the receiving party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A;

13. The restrictions contained in this schedule 4 shall remain in force without limit in time in respect of personal data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly agreed between the parties, these clauses shall remain in force for a period of 10 years after the end of the study at the participating organisation.

Appendix 1 – staff signature and delegation log

(Template version 4.4)

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. Provides data on adverse events where necessary	9. Enter other task here	14. Enter other task here	19. Enter other task here
5. Provide 15 months of prescription data	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:

1. 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.
2. 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 4.4)

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 may publish reports on our website explaining how we will address the themes raised. Any published reports 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 in any publication 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 any report.

Organisational responses only

If you do not wish your organisational response, and any quotes used from it, to be identified in any report or publications,

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

Individual responses only

I am responding primarily as: (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 report or publication relating to this document:

I am willing for my response, and quotes used from it, to be made identifiable in any report or publication relating to this document:

Select 'yes' or 'no'

All responses

I am willing to be contacted by the HRA for further information in relation to my comments.
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 or HCRW staff to contact you about your submission. The HRA and HCRW take 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 General Data Protection Regulation and the Data Protection Act 2018 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 2018 (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 or HCRW.

Template Version No: 1.2

Organisation Information Document – Non-Commercially Sponsored Studies

(Template version: 1.2)

Guidance on Using This Document

Please use this document to create the outline Organisation Information Document/s that you will submit with your IRAS Form. In most instances the Organisation Information Document should be localised before sharing with participating NHS / HSC organisations.

Questions/items marked with an asterisk * (Questions 1-3, 5, 8 and 12-15, as well as items throughout the appendices as applicable) must be completed prior to submission of the IRAS Form in all cases. Only if the localised Organisation Information Document is to be used as the Agreement between the parties should the Sponsor or authorised delegate check the relevant check-boxes at the top of each subsequent appendix and complete the authorisation section.

Items marked with a caret ^ are completed by the participating NHS / HSC organisation, after the Local Information Pack is shared and where relevant.

Remaining questions may be answered on the localised Organisation Information Document either by the Sponsor or authorised delegate prior to sharing the Local Information Pack, or by the participating NHS / HSC organisation (or collaboratively between the two) after the Local Information Pack is shared, as appropriate.

To provide an answer in the document, click in a box with the grey text (click here to enter text), choose the relevant option if presented with a drop-down list or click in the box if presented with a check-box ☐.

A separate guidance document is provided and should be consulted prior to completion of this document. Please also read the question specific guidance where present.

We welcome your feedback on the use of the UK Local Information Pack. If you would like to provide feedback, please take the UK Local Information Pack Survey.

Study Information

1.* **IRAS Project ID**	255698
2.* **Full Title of the Study**	The Gentle Years Yoga Trial
3.* **Legal Name(s) of Sponsor/Co-Sponsors/Joint-Sponsors**	University of Northumbria at Newcastle

4. Contact details of person acting on behalf of Sponsor for questions relating to study set up. Please enter details of the person who is the Sponsor's main point of contact for all correspondence on setting up the study at this NHS / HSC organisation. This contact may be the Sponsor, a Study Manager, Clinical Research Scientist or Study Coordinator. Where a Contract Research Organisation (CRO) or Clinical Trials Unit (CTU) has been delegated to handle set up on behalf of the Sponsor, the contact at the CRO or CTU should be named here.

Name	[redacted]
Telephone Number	[redacted]
Email Address	[redacted]

5.* Are all participating NHS / HSC organisations undertaking the same protocol activities?

No

If 'No' give details of the activities taking place at NHS / HSC organisations that you will use this outline Organisation Information Document with. Additional outline Organisation Information Documents may be required for NHS / HSC organisations undertaking different activities.

1. Carry out a database search to identify potential participants – READ codes will be provided to support this
2. Provide details to a third party mailing service called Docmail who will mail out invitation packs to patients
3. GP willing to confirm eligibility of their patient(s) when approached by York Trials Unit. YTU will only contact GP's after receipt of a valid consent form and screening questionnaire from patients.
4. Willing to provide data on adverse events when contacted by York Trials Unit. YTU will only contact GP's when they are unable to get in touch with the participant.

Participating NHS / HSC Organisation Information

6. Name of Participating NHS / HSC Organisation. If this Organisation Information Document is being used as an Agreement the name must be entered prior to agreement.
Enter name of participating NHS / HSC Organisation
7. Location/s*:* Please provide detail below where it is planned to undertake the research only at specified locations with the participating NHS / HSC organisation (i.e. hospital(s), GP Practice(s) and/or Research Unit(s))**.** It is not intended that the level of detail provided here captures individual departments within the participating NHS / HSC organisation.

Location (enter text below)	**Activity** (enter text below)
GP Practice	All activities detailed above

8*. What is the role of the person responsible for research activities at the participating NHS / HSC organisation? • Principal Investigators are expected to be in place at participating NHS / HSC organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single centre studies where the Chief Investigator will also be the Principal Investigator. • Where this is not the case, local collaborators are expected to be in place where central study staff will be present at the participating organisation to undertake research procedures (the role of the Local Collaborator is to facilitate the presence of Sponsor / CRO research staff). • Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at the participating NHS / HSC organisation, select Chief Investigator.
Chief Investigator
9. Contact details of person responsible for research activities at this participating NHS / HSC organisation as indicated in question 8 (if known). If known, please enter the details of the person you have spoken to about their role in this study at this participating NHS / HSC organisation. If unknown, please leave blank and that person can be identified and listed here during the setup of the study.

Name	Enter name
Post / Job Title	Enter post
Name of Employing Organisation	Enter name of organisation
Email Address	Enter email address
Telephone number	Enter telephone number

Timescales

10. Predicted Start and End Dates of the Study at this Participating NHS / HSC Organisation The Sponsor or authorised delegate should propose a date on which it intends to start and complete research activity at this participating NHS / HSC organisation. Alternatively, this may be left blank when the Local Information Pack is shared, for agreement during study set up at the Participating NHS / HSC Organisation.	
Predicted Start Date (activities at this organisation)	Select predicted start date
Predicted End Date (activities at this organisation)	Select predicted end date
For many types of study the following dates are not applicable and this may be stated in answer. Where they are applicable, they should be provided by the Sponsor or authorised delegate before sharing the Local Information Pack, as indicative targets for agreement, or they may be negotiated between Sponsor or authorised delegate and participating NHS / HSC organisation after sharing the pack.	
Predicted Site Initiation Visit Date	N/A
Predicted Start Date for participant recruitment	Select predicted start date for participant recruitment
Predicted End Date for participants recruitment (i.e. when the study moves into "follow up" activities.)	Select predicted end date for participant recruitment
Predicted End Date for all study activities (i.e. "last patient visit" completed and study is ready to be archived.)	31/03/2023

Participant Numbers

11. How many research participants are expected at this participating NHS / HSC organisation? For studies not directly involving human participants, please indicate the number of samples or data-sets to be obtained. Please state if number of participants is per month, per year, overall, etc.
~ 16-30 participants overall per site

Study set up and delivery arrangements at Participating NHS / HSC Organisations

12*. The following are needed at the participating NHS / HSC organisation to deliver the study: e.g. specific equipment, patient/participant groups, service support, nursing time, etc. Please detail any specific requirements for participating NHS / HSC organisations to deliver this study, including by clarifying any requirements on participating NHS / HSC organisations relating to monitoring / self-monitoring, e.g. requirements for staff signature and delegation logs to be returned to the Sponsor and/or any particular access requirements that the Sponsor may have that it wishes to bring to the attention of the participating NHS / HSC organisation, likelihood of staff not employed at the participating NHS / HSC organisation coming on site, etc.
1. Be willing to send patient details to docmail to do the mail out 2. Have a GDPR compliant contract with docmail 3. Willing to sign this document as a contract with the sponsor and YTU 4. Send invoices to YTU for payment
13*. The following training will be provided by the Sponsor or authorised delegate for local research team members. Where only specific team members (e.g. the Principal Investigator) will receive this training, this should be specified.
There is no mandatory training. Support will be organised with the CRN regarding the use of docmail if requested.
14*. The Sponsor expects that local research team members will have the following skills and where they do not have those skills that they will undertake the relevant training before undertaking the relevant study activities. 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, for example, that when they expect **training in Good Clinical Practice** for appropriate team members where the study is a Clinical Trial of an Investigational Medicinal Product, they will accept UK nationally recognised GCP training, training recognised on the **Transcelerate mutual recognition scheme**, etc.
N/A
15*. The following funding/resources/equipment, etc. is to be provided to this participating NHS / HSC organisation. The Sponsor should answer this question whether this Organisation Information Document is to be used as the Agreement with the participating NHS / HSC organisation or not. Where the document is intended as the Agreement, further detail should be provided in Appendix 2.

Identification of Patients

- Local Coordination and set up (Research Cost) by Practice Manager (0.5 hours @ £23.21 p/hour) and GP (0.5 hours @ £90.00 p/hour) = £56.61
- Preparation for Database search and mail out – Level 2 (Service Support Cost) by Practice Manager *
- Database search – Level 1 (Service Support Cost) by Practice Manager *

Patient Invite

- Check lists for exclusions (Service Support Cost) by GP *
- Send invite letters via docmail (Research Cost) by Admin staff (6 hours @ £13.29 p/hour) = £79.74
- Final check for suitability (Service Support Cost) by GP *

Reporting Safety Events

- Reporting Safety Events (Service Support Cost) by GP (if applicable) *

** Your Local Clinical Research Network (LCRN) will advise on Service Support Costs for these activities*

Appendices

(Contents)

The sponsor or authorised delegate should answer the question at the top of Appendix 1 and, if it intends that this Organisation Information Document will be incorporated into an exchange of correspondence to form the Agreement ("Agreement") between itself and the participating NHS / HSC organisation, the questions that appear at the top of each subsequent appendix.

Appendix 1: General Provisions

***Does the Sponsor intend that this Organisation Information Document forms the Agreement between itself and the participating NHS / HSC Organisation, or has a separate site agreement been provided?**	Organisation Information Document

It is recommended that the Organisation Information Document is used as the Agreement between Sponsor and participating NHS / HSC organisation for studies that are not clinical trials or investigations. The model Non-Commercial Agreement (mNCA) should be used for clinical trials or investigations.

Where the Organisation Information Document is to be used as the Agreement between the Sponsor and participating NHS organisation (hereafter singly "Party" or collectively the "Parties"), this document forms a formal legal contract between the Parties. In all cases where this document is the Agreement between the Parties, this Appendix 1 applies in full.

Additionally, the Sponsor or authorised delegate should use the questions at the top of each subsequent appendix to indicate whether or not that appendix also forms part of the Agreement.

Text highlighted in yellow is optional, including where alternative versions of the same clause may be used. The applicable option/s should be selected and text not to be used should be deleted prior to IRAS submission. No changes should be made to any text that does not appear in yellow highlight.

1. OBLIGATIONS OF THE PARTIES

1.1. The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to this Agreement including to the performance of the study. The Parties agree to comply with the World Medical Association Declaration of Helsinki, titled "Ethical Principles for Medical Research Involving Human Subjects" (where applicable) and the UK Policy Framework for Health and Social Care Research. The Parties shall conduct the study in accordance with:

1.1.1. the Protocol, including appropriately made amendments thereto (which is/are hereby incorporated into this Agreement by reference);

1.1.2. the terms of all relevant permissions and approvals. These may include, but are not limited to the terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee, where applicable.

1.2. The Parties shall carry out their respective responsibilities in accordance with this Agreement.

1.3. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants and study personnel.

1.4. The Sponsor shall, on the giving of reasonable prior written notice to the Participating NHS / HSC Organisation, have the right to audit the Participating NHS / HSC Organisation's compliance with this Agreement. The Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access, during normal working hours to the Participating NHS / HSC Organisation's premises and to all relevant documents and other information relating to the study.

1.5. The Participating NHS / HSC Organisation shall;

1.5.1. promptly notify the Sponsor should any responsible body conduct or give notice of intent to conduct any inspection at the Participating NHS / HSC Organisation in relation to the study;

1.5.2. allow the Sponsor to support the preparations for such inspection; and

1.5.3. following the inspection, provide the Sponsor with the results of the inspection relevant to the study. The Sponsor will be responsible for sharing such results with the funder if required.

1.6. In accordance with participant consent, the Participating NHS / HSC Organisation shall permit the Sponsor's appointed representatives and any appropriately appointed monitor access to all relevant data for monitoring and source data verification. The Parties agree that such access will be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the study, reasonable access to relevant members of staff at the Participating NHS / HSC Organisation and the right to examine any procedures or records relating to the study, subject at all times to clause 2.3 of this appendix. The Sponsor will alert the Participating NHS / HSC Organisation promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the study.

2. LIABILITIES AND INDEMNITY

2.1. Nothing in this clause 2 shall operate so as to restrict or exclude the liability of a Party in relation to statutory or regulatory liability (including but not limited to breach of the data protection legislation), death or personal injury caused by the negligence or wilful misconduct of that Party or its agent(s), fraud or fraudulent

misrepresentation or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.

2.2. Where a Party is a non-NHS/HSC organisation, or an NHS/HSC organisation that is not a member of an NHS indemnity scheme, then that Party shall maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the study, in respect of any claims brought by or on behalf of a participant. Where the Party is an NHS/HSC organisation and is a member of an NHS indemnity scheme, it shall maintain its membership therein or otherwise ensure it has appropriate cover against claims arising as a result of clinical negligence by the Party and/or its agents brought by or on behalf of the participants. Each Party shall provide to the other such evidence of their insurance or equivalent indemnity cover maintained pursuant to clause 2.2 as the other Party shall from time to time reasonably request, such evidence might comprise confirmation that an NHS/HSC organisation is a member of one of the NHS indemnity schemes.

2.3. Subject to clauses 2.4, 2.5, 2.6, 2.7 and 2.8, the Sponsor shall indemnify the Participating NHS / HSC Organisation and its agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands ("Claims") to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Sponsor, and/or contracted third party, in its performance of this Agreement or in connection with the study.

2.4. Subject to clauses 2.3, 2.5, 2.6 and 2.8, the Participating NHS / HSC Organisation shall indemnify the Sponsor and its respective agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Participating NHS / HSC Organisation, or its agents, in its performance of this Agreement or in connection with the study.

2.5. An indemnity under clauses 2.3 or 2.4 shall only apply if the indemnified Party:

2.5.1. informs the Party providing the indemnity in writing as soon as reasonably practicable following receipt of notice of the claim or proceedings;

2.5.2. upon the indemnifying Party's request and at the indemnifying Party's cost gives the indemnifying Party full control of the claim or proceedings and provides all reasonable assistance; and

2.5.3. makes no admission in respect of such claim or proceedings other than with the prior written consent of the indemnifying Party.

2.6. Any indemnity under clauses 2.3 or 2.4 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from the negligent acts or omissions or wilful misconduct or breach of statutory duty of the indemnified Party.

2.7. The indemnity under clause 2.3 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from:

2.7.1. Participating NHS / HSC Organisation carrying out a treatment or procedure that would be routinely undertaken at or for that Participating NHS / HSC Organisation as part of National Health Service treatment; or

2.7.2. Participating NHS / HSC Organisation preparing, manufacturing or assembling any equipment which is not done in accordance

2.7.2.1. with the protocol; or

2.7.2.2. with written instructions of the manufacturer; or

2.7.2.3. (where such instructions differ from the instructions of the manufacturer) other written instructions of the Sponsor.

2.8. No Party shall be liable to another in contract, tort/delict, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement.

2.9. If a Party incurs any loss or damage (including costs and expenses) ("Loss") arising or resulting from this Agreement and:

2.9.1. All Parties are NHS bodies as defined in Section 9(4) of the National Health Service Act 2006 or Section 17 of the National Health Service (Scotland) Act 1978 or Section 7 (4) of the NHS (Wales) Act 2006 or Articles 16 and 26 of the Health and Personal Social Services (Northern Ireland) Order 1972, which established the Boards and Central Services Agency respectively and Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991: which established Trusts in Northern Ireland as appropriate; or

2.9.2. One or more Party is a NHS body and the other Party (ies) is a NHS Foundation Trust; or

2.9.3. All Parties are NHS Foundation Trusts;

Then clauses 2.10, 2.11 and 2.12 shall apply.

2.10. If all Parties are NHS bodies / NHS Foundation Trusts in England, Wales or Northern Ireland and are indemnified by the same indemnity scheme (being one of the NHS Resolution's clinical negligence schemes or the Welsh Risk Pool or the Clinical Negligence Fund in Northern Ireland) and the Party incurring any loss can recover such loss under one of the indemnity schemes, then such Party shall rely on the cover provided by the indemnity scheme and not seek to recover the Loss from the other Party (ies). Where the other Party (ies) caused or contributed to the Loss, it undertakes to notify the relevant indemnity scheme(s) to take this into account in determining the future levies of all Parties in respect of the indemnity schemes.

2.11. If:

2.11.1. The Parties are members of the same indemnity scheme in England, Wales or Northern Ireland and the Party incurring the Loss is not indemnified for that Loss by its indemnity schemes; or

2.11.2. All Parties are NHS bodies in Scotland; or

2.11.3. The Parties are NHS bodies/Foundation Trusts established in different jurisdictions within the United Kingdom;

Then the Parties shall apportion such Loss between themselves according to their respective responsibility for such Loss.

2.12. If one or more Parties are NHS Foundation Trusts and the Party incurring the Loss is not responsible for all or part of the Loss and is not indemnified in respect of the Loss by one of the indemnity schemes then the Party incurring the Loss shall be entitled to recover the Loss from the other Party (ies) pursuant to the provisions of this Agreement.

2.13. Subject to clause 2.1 and 2.7 the liability of the Participating NHS / HSC Organisation to the Sponsor and the liability of the Sponsor to the Participating NHS / HSC Organisation arising out of or in connection with any breach of this Agreement or any act or omission of either Party in connection with the performance of the study should be the greater of the amount of fees payable by the Sponsor to the Participating NHS / HSC Organisation under this Agreement or one hundred thousand (£100,000 GBP) pounds. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under clauses 2.3 and 2.4.

2.14. Notwithstanding clause 2.13, in the case of equipment loaned by or on behalf of the Sponsor to the Participating NHS / HSC Organisation for the purposes of the study, the Participating NHS / HSC Organisation's liability for damage to or loss of that equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the replacement value of the equipment.

3. PUBLICITY

3.1. Neither Party shall use the name, logo or registered image of the other Party or the employees of such other Party in any publicity, advertising or press release without the prior written approval of an authorised representative of that Party.

3.2. The content and timing of any publicity, advertising or press release shall be agreed by both Parties, such agreement not to be unreasonably withheld.

4. PUBLICATION

4.1. In accordance with all relevant laws, regulations and codes of practice, it is agreed that the Sponsor has an obligation to and shall publish the results of the full study and that the Participating NHS / HSC Organisation shall not publish any study data, including through presentation or submission of an abstract, without the prior permission in writing from the Sponsor (which shall not be unreasonably withheld or delayed).

5. FREEDOM OF INFORMATION

5.1. 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) working days after receiving the request.

5.2. 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.

5.3. 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) working days' notice of its intended disclosure.

6. CONFIDENTIALITY

6.1. Subject to clause 5 above, the Participating NHS / HSC Organisation agrees to treat the results, excluding any clinical data of the study, as confidential information of the Sponsor and the Sponsor agrees to treat personal data and confidential patient information as confidential information.

6.2. The receiving Party agrees:

6.2.1. 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

6.2.2. 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 7.2.

6.2.3. To use confidential information solely in connection with the operation of the Agreement and not otherwise, except in the case where the confidential information is personal data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.2.4. Not to disclose confidential information in whole or in part to any person without the disclosing Party's prior written consent or, where the confidential information is personal data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.3. The provision of clause 7.2 shall not apply to the whole or any part of the confidential information that is:

6.3.1. lawfully obtained by the receiving Party free of any duty of confidentiality;

6.3.2. 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 7.2.1 or 7.2.2);

6.3.3. in the public domain (other than as a result of a breach of clause 7.2.1 or 7.2.2);

6.3.4. independently discovered by employees of the receiving Party without access to or use of confidential information;

6.3.5. necessarily disclosed by the receiving Party pursuant to a statutory obligation;

6.3.6. disclosed with prior written consent of the disclosing Party;

6.3.7. necessarily disclosed by the receiving Party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A;

6.3.8. published in accordance with the provisions of clause 5.

6.4. The restrictions contained in clauses 7.2 shall remain in force without limit in time in respect of personal data and any other information 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 2: Finance Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select one of the following.	
*There are no funds/resources/equipment, etc. being provided to this participating NHS / HSC organisation by the Sponsor. This appendix should be left blank.	☐
*This study involves the provision of funding/resource/equipment, etc. to the participating NHS / HSC organisation. This finance appendix forms part of the Agreement between the participating NHS / HSC organisation and the Sponsor.	

A. Financial Arrangements

The overall, study-wide recruitment for this study is competitive with a maximum figure of 586 Participants. Once this target has been reached, the Sponsor will notify the Participating NHS / HSC Organisation. No additional per participant payments will be made by the Sponsor to the Participating NHS / HSC Organisation for participants consented after such notification becomes effective.

	*Area of Cost	*Payment (£ Sterling)
1*	Local Coordination and set up (Research Cost) by Practice Manager	£56.61
2*	Preparation for Database search and mail out – Level 2 (Service Support Cost) by Practice Manager	Click here to enter text To be confirmed by your LCRN
3*	Database search – Level 1 (Service Support Cost) by Practice Manager	To be confirmed by your LCRN
4*	Check lists for exclusions (Service Support Cost) by GP	To be confirmed by your LCRN
5*	Send invite letters via docmail (Research Cost) by Admin staff	£79.74
6*	Final check for suitability (Service Support Cost) by GP	To be confirmed by your LCRN
7*	Reporting Safety Events (Service Support Cost) by GP	To be confirmed by your LCRN

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment of the agreed costs on presentation of a VAT invoice in which the VAT is stated as a separate item. Such invoices should quote the Participating NHS / HSC Organisation's VAT registration number. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

Schedule of payments and details of payment arrangements

*Invoices to be submitted at the end of the recruitment wave and then again at the end of follow up to:

For Research Costs Only:

The Gentle Years Yoga Trial Coordinator
York Trials Unit
Department of Health Sciences
Faculty of Science
ARRC Building, Lower Ground Floor
University of York
Heslington, York
YO10 5DD

OR

gyy-trial@york.ac.uk

^Payment to be made by cheque payable to:

[Insert NAME OF PARTICIPATING NHS / HSC ORGANISATION]

^and remitted to:

[Insert JOB TITLE/POSITION]

[Insert ADDRESS]

^Or arrange BACS Transfer to: N/A

^Sort code: N/A

^Account: N/A

^And send the relevant paper work to N/A at the above address

Invoices must be paid promptly within 30 days of receipt. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding has been irrecoverably reclaimed by the funder as a result of such delay or inadequacy.

For Service Support Costs Only

Your LCRN will advise on payment arrangement for these costs

B. Supplies Arrangements

Any equipment, materials, consumables, software or other items being provided by the Sponsor or procured by the participating organisation for use in the study shall be specified below.

Note 1: Parties should complete the table below. If the Participating NHS / HSC Organisation is to procure any items and is to be reimbursed by the Sponsor this should be specified in this appendix. Similarly if the Participating NHS / HSC Organisation is to pay the Sponsor for any items provided to the Participating NHS / HSC Organisation by or on behalf of the Sponsor this should be specified in this appendix.

Note 2: Parties should specify in this appendix, as appropriate, arrangements for:

- Ownership of items
- Insurance
- Storage instructions
- Instructions for use, return and/or destruction
- Any training to be provided
- Maintenance of equipment

Item	**Quantity**	**Frequency of supply**	**Responsibility to supply/procure (either Sponsor or Participating NHS / HSC Organisation only)**
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text

Appendix 3: Material Transfer Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select one of the following	
*This study does not involve the transfer of human biological material ("Material") from this participating NHS / HSC organisation to the Sponsor or its agents. This appendix does not form part of this Agreement.	
*This study involves the transfer of human biological material ("Material") from this participating NHS / HSC organisation to the Sponsor or its agents. These provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	☐

Material, as used in this appendix, means any clinical biological sample or portion thereof, derived from participants, including any information related to such Material, supplied by the Participating NHS / HSC Organisation to the Sponsor or its nominee.

1. In accordance with the protocol, the Participating NHS / HSC Organisation shall send Material to the Sponsor or, in accordance with provision 7 below, to a third party nominated by the Sponsor.
2. The Participating NHS / HSC 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 (as the case may be)) and as required by the protocol.
3. 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.
4. The Sponsor shall ensure, or procure through an agreement with the Sponsor's nominee as stated in provision 1 above that:
   4.1. the Material is used in accordance with the protocol, the consent of the participant, and the ethics approval for the study;
   4.2. the Material is handled and stored in accordance with applicable law;
   4.3. 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.
5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.

6. The Participating NHS / HSC Organisation and the Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this appendix.
7. To the extent permitted by law the Participating NHS / HSC Organisation and its staff shall not be liable for any consequences of the supply to or the use by the Sponsor of the Material or of the supply to or the use by any third party to whom the Sponsor subsequently provides the Material or the Sponsor's nominee as stated in provision 1 above, save to the extent that any liability which arises is a result of the negligence of the Participating NHS / HSC Organisation.
8. The Sponsor undertakes that, in the event that Material is provided to a third party in accordance with provision 2 above, it shall require that such third party shall undertake to handle any 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 this appendix.
9. Any surplus Material that is not returned to the Participating NHS / HSC 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 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

**These provisions do not remove the need for the Sponsor to clearly lay out in their protocol (and to potential participants in the participant information) at a minimum the following information for all 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 and, 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: www.hra.nhs.uk*

Appendix 4: Data Processing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select one of the following.	
*This study does not involve any processing of personal data by this participating NHS / HSC organisation on behalf of the Sponsor. This appendix does not form part of this Agreement.	☐
*This study involves processing of personal data by this participating NHS / HSC organisation on behalf of the Sponsor. These provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation. For the avoidance of doubt, when used, these provisions are intended to form a legally binding contractual obligation for the purposes of compliance with the GDPR, specifically GDPR Article 28 (3).	

For the purposes of the data protection legislation, the Sponsor is the controller and the Participating NHS / HSC Organisation is the Sponsor's processor in relation to all processing of personal data that is processed for the purpose of this study and for any future research use under the controllership of the Sponsor, that would not have taken place but for this Agreement regardless where that processing takes place.

1. The Parties acknowledge that whereas the Sponsor is the controller in accordance with Clause 1 of this appendix, the Participating NHS / HSC Organisation is the controller of the personal data collected for the purpose of providing clinical care to the participants. This personal data may be the same personal data, collected transparently and processed for research and for care purposes under the separate controllerships of the Sponsor and Participating NHS / HSC Organisation.
2. Where the Participating NHS / HSC Organisation is the Sponsor's processor and thus where the processing is undertaken by the Participating NHS / HSC Organisation for the purposes of the study, Clauses 5.a. to 5.j below will apply. For the avoidance of doubt, such Clauses do not apply where the Participating NHS / HSC Organisation is processing the participant personal data as a controller.
3. The Participating NHS / HSC Organisation agrees only to process personal data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the study and to ensure the Sponsor’s compliance with the data protection legislation;
4. The Participating NHS / HSC Organisation agrees to comply with the obligations applicable to processors described by Article 28 GDPR including, but not limited to, the following:

a. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the controller by Article 28(1);

b. to not engage another processor without the prior written authorisation of the Sponsor (Article 28(2));

c. to process the personal data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Participating NHS / HSC Organisation shall notify the Sponsor before processing, or as soon as possible after processing if legislation requires that the processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a)).;

d. to ensure that personnel authorised to process personal data are under confidentiality obligations (Article 28(3b));

e. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));

f. to respect the conditions described in Article 28(2) and (4) for engaging another processor (Article 28(3d));

g. to, taking into account the nature of the processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising data subjects' rights (Article 28(3e));

h. to assist the controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the processing and the information available to the Participating NHS / HSC Organisation (Article 28(3f));

i. to, at the choice of the Sponsor, destroy or return all personal data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (Article 28(3g)) or where that personal data is held by the Participating NHS / HSC Organisation as controller for the purpose of clinical care or other legal purposes; and

j. to maintain a record of processing activities as required by Article 30(2) GDPR.

5. The Participating NHS / HSC Organisation shall ensure that:

a. its agents do not process personal data except in accordance with this Agreement (and in particular the protocol);

b. it takes all reasonable steps to ensure the reliability and integrity of any of its agents who have access to the personal data and ensure they:

i. are aware and comply with the Participating NHS / HSC Organisation 's duties under this clause;

ii. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and

iii. are informed of the confidential nature of the personal data and understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.

6. The Participating NHS / HSC Organisation agrees to:

   a. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Participating NHS / HSC Organisation's compliance with the obligations described by this Appendix, data protection legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the participating site and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and

   b. obtain prior agreement of the Sponsor to store or process personal data outside the European Economic Area.

7. Where the Participating NHS / HSC Organisation stores or otherwise processes personal data outside of the European Economic Area as the Sponsor's processor, it warrants that it does so in compliance with the Data Protection Legislation.

Appendix 5: Data Sharing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS/HSC organisation, please select one of the following	
*This study does not involve the transfer of personal data from this participating NHS / HSC organisation to the Sponsor or its agents, nor is there transfer of confidential information between the Parties. This appendix does not form part of this Agreement.	☐
*This study involves the transfer of personal data from this participating NHS / HSC organisation to the Sponsor or its agents, and/or there is transfer of confidential information between the Parties. These provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	

1. Personal data shall not be disclosed to the Sponsor by the participating NHS / HSC 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.
2. The Sponsor agrees to use personal data solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,
   2.1. Not to disclose personal data to any person except in accordance with applicable legal requirements and codes of practice.
3. The Sponsor agrees to comply with the obligations placed on a controller by the data protection legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to processing of personal data (Article 5 GDPR)
4. The Sponsor agrees to ensure persons processing personal data under this Agreement are equipped to do so respectfully and safely. In particular:
   4.1. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the participating NHS / HSC organisation) processing personal data understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.
   4.2. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating NHS / HSC Organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
5. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular,

5.1. To ensure that personal data are only accessible to persons who need it for the purposes of the study and to remove access as soon as reasonably possible once it is no longer needed.
5.2. To ensure all access to personal data on IT systems processed for study purposes can be attributed to individuals.
5.3. To identify, review and improve processes which have caused breaches or near misses, or which force persons processing personal data to use workarounds which compromise data security.
5.4. To adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
5.5. To take action immediately following a data breach or near miss.

6. The Sponsor agrees to ensure personal data are processed using secure and up to date technology. In particular,
6.1. To ensure no unsupported operating systems, software or internet browsers are used to support the processing of personal data for the purposes of the study.
6.2. To put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials.
6.3. To ensure IT suppliers are held accountable via contracts for protecting personal data they Process and for meetings all relevant information governance requirements.

Appendix 6: Intellectual Property Rights

Where this Organisation Information Document is to be used as the Agreement between Participating NHS / HSC organisation, please select one of the following*	
*This study does not require the protection of background intellectual property rights, nor is there potential for the generation of new intellectual property. This appendix does not form part of this Agreement.	
*This study requires the protection of background intellectual property rights, and / or there is potential for the generation of new intellectual property. These provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	☐

1. All background intellectual property rights (including licences) and know how and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party's rights.
2. All intellectual property rights and know how in the Protocol, and in the study data, excluding clinical procedures developed or used by the Participating NHS / HSC Organisation independently of the Study, shall belong to the Sponsor. The Participating NHS / HSC Organisation hereby assigns all such intellectual property rights, and undertakes to disclose all such know how, to the Sponsor.
3. Subject to clause 1 and 2, all intellectual property rights deriving or arising from the Material or any derivations of the Material provided to the Sponsor by the Participating NHS / HSC Organisation shall belong to the Sponsor.
4. At any time within the duration of the Study, the Participating NHS / HSC Organisation shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the intellectual property rights in the Sponsor. To give effect to this clause 4, the Participating NHS / HSC Organisation shall ensure that its agents involved in the Study assign such intellectual property rights falling within clauses 2 and 3 and disclose such know how to the Participating NHS / HSC Organisation.
5. Subject to this Clause 5 and Clause 6, nothing in this Appendix shall be construed so as to prevent or hinder the Participating NHS / HSC Organisation from using its own know how or clinical data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor, or their funder. This clause 5 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results. Any study data not so published remains the confidential information of the Sponsor, or their funder.
6. The Participating NHS / HSC Organisation may, with the prior written permission of the Sponsor (such permission not to be unreasonably withheld), use study data gained during the performance of the Study, at its own risk, in the furtherance of its normal

activities of commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor or their funder. This clause 6 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the Study.

Authorisation When Using This Organisation Information Document as An Agreement

(when used as an Agreement, the Participating NHS Organisation is a "Party" to the Agreement and the Sponsor is a "Party" to the Agreement – collectively the "Parties").

Authorisation on behalf of Participating NHS / HSC Organisation It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the Sponsor and participating NHS / HSC organisation. Instead, Sponsors are expected to accept confirmation by email from an individual empowered by the Participating NHS / HSC Organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).	
^ The Participating NHS / HSC Organisation confirms (by checking the box) that the Principal Investigator, where one is required, is aware of and has agreed to discharge their responsibilities in line with the UK Policy Framework for Research and Social Care..	☐
^ The Participating NHS / HSC Organisation has considered and mitigated any conflict/s of interest declared by the principal investigator.	Select from drop down
If yes, please detail conflict of interest	

*** Authorised on behalf of Sponsor by:**	
Name	Enter name
Job Title	Enter job title
Organisation Name	Enter organisation name
Date	Select date of authorisation
^ Authorised on behalf of Participating NHS / HSC Organisation by:	
Name	Enter name
Job Title	Enter job title
Organisation Name	Enter organisation name
Date	Select date of authorisation