Guidance on the use of the UK Model Agreement for Non-Commercial Research (mNCA)

April 2026, Version 3.0

Contents

Context and use of the mNCA

1. Introduction

1.1 Before an externally sponsored research Study may commence at a Trial Site, the Sponsor and Trial Site should agree and document the activities to be undertaken by the Trial Site, along with other key arrangements. These include arrangements for insurance, indemnity, intellectual property, data processing, data transfer, governing law, funding, etc.

1.2 Where that Trial Site will subcontract or otherwise delegate activities that the sponsor has contracted it to deliver, these activities and related arrangements should be similarly agreed and documented between Trial Site and the subcontracted party.

1.3 For non-commercial, interventional research studies, the mNCA has been developed to meet the need for clear, consistent, fair and documented agreement between Sponsor and Trial Site. As a standardised and established template, that removes the need for study by study review and negotiation, mNCA provides for streamlined Trial Site set-up and research delivery, whilst protecting the rights of all parties.

1.4 The non-commercial hub and spoke agreement has been developed as a subcontract of the mNCA. The hub and spoke agreement is for use where the Trial Site subcontracts activities it has been contracted to deliver by the Sponsor (where those activities will be overseen by the Trial Site's Principal Investigator). As with mNCA, use of a standard template is designed to streamline set-up and protect all parties. In addition, the hub and spoke template allows for context specific arrangements for cross-organisation PI oversight to be documented.

1.5 In the NHS in England, Northern Ireland[1] or Wales, provision of signed mNCA by the Trial Site to the Sponsor confirms that the Trial Site is ready to commence the contracted research study. Provision of signed hub and spoke agreement by the

[1] Throughout this guidance and the mNCA and non-commercial hub and spoke agreement template, references to NHS should be construed to include references to HSC in Northern Ireland

Other Trial Site to the Trial Site confirms that the Other Trial Site is ready to commence the subcontracted research study. In either case in the NHS in Scotland, management permission is also needed from the Trial Site / Other Trial Site.

2. Use of the mNCA

2.1 mNCA should be used for non-commercial, interventional research studies in the NHS. It may also be used, at the discretion of the Parties, in non-NHS health and social care contexts;

2.1.1 Interventional research studies include Clinical Trials of Investigational Medicinal Products (CTIMPs), regulated and non-regulated clinical investigations of medical devices, combined CTIMP / device studies and other clinical trials (for example, trials of surgical procedures). The non-commercial Organisation Information Document is the template agreement intended for contracting non-interventional, non-commercial studies in the NHS;

2.1.2 The key element that makes mNCA non-commercial is that the Study is not being undertaken primarily to generate IPR for commercial exploitation by a commercial entity. The Study is to be managed (that is to say, contracted and cost-recovered, in accordance with AcoRD principles) as non-commercial. The ultimate source of funding could be from a commercial entity (i.e. an Investigator Initiated Trial (IIT)) but that entity is not a Party to the mNCA. Template agreements for commercial CTIMPs, commercial clinical investigations of medical devices and commercial non-interventional research are available on the IRAS Help website.

2.2 mNCA may be used with Trial Sites established in any of the four UK nations and non-commercial Sponsors either established in the UK or elsewhere. The mNCA takes into account jurisdictional differences in its wording.

2.3 The mNCA has been developed to ensure that only project-specific alterations are necessary (that is, where indicated in yellow highlight). The terms and conditions have been drafted to cover the essential legal provisions in relation to all applicable types of research project and these should not be amended. The template includes detailed instructions on preparing the Agreement prior to it being shared with / submitted to national coordinating functions and Trial Site research management offices.

2.4 Proposals to alter the mNCA, or to use a bespoke agreement, are likely to result in lengthy delay, whilst additional review and negotiation occurs.

2.5 The mNCA is likely to form one of a number of agreements relating to a project. Other agreements may include honorary research contracts, an agreement between Sponsor and funder, agreements between Sponsor and collaborators, agreements between Sponsor and other Investigator Sites (additional mNCAs) and agreements governing activities subcontracted by the Trial Site to Other Trial Sites (hub and spoke agreements).

3. Parties to the Agreement

3.1 mNCA is drafted as a two (or more than two) party agreement, those Parties being the Trial Site and the organisation which is acting as Sponsor (or Sponsors, where the Study is joint or co-sponsored) in the UK.

3.2 The Trial Site is the legal entity that employs (or has other appropriate arrangements with) the Principal Investigator and which has a duty of care for some or all of the research activity to be overseen by that Principal Investigator. The Trial Site could be an NHS or HSC Trust, Foundation Trust, Health Board, a General Practice or other provider of primary, secondary or tertiary health and / or social care and / or health and / or social care research services.

3.3 The Sponsor(s) could be one (or more) of a number of different types of public sector or charitable body, such as an NHS organisation, a university, a government department, research council or research funder. The 2018 version of mNCA introduced provision for Single-Sponsor, Co-Sponsor and Joint-Sponsor arrangements.

3.4 Where there are Co-Sponsors, their respective roles should be clearly stated in Schedule 2 (under Joint-Sponsorship, all responsibilities are held jointly by both Sponsors). Co-Sponsors should clarify between themselves their respective rights and obligations that arise under the mNCA. For ease of managing the Study, the mNCA states that each Sponsor has the authority to act on behalf of the other Sponsor(s) and consent, agreement, etc. given by one Sponsor is deemed to have been given on behalf of them all. Should Sponsors wish to vary any such provision, it should be done by way of a separate agreement between the Sponsors.

3.5 Each Party should nominate an appropriately authorised individual to sign the contract on their behalf. In the NHS, this is likely to be a Director of R&D, or another senior person authorised by or on behalf of the NHS organisation's Board, partners, or equivalent. The signatory is unlikely to be the PI, or other member of the research team (except where such an individual also holds the position of R&D Director, or similar). Sponsors should take care to enter into agreements only with persons appropriately authorised by the Trial Site.

3.6 The organisation which is acting as Sponsor(s) for the Study in the UK should be Party to the Agreement, regardless of whether they are established within the UK and regardless of whether they have authorised a third party to sign the Agreement on their behalf. This organisation must match the Sponsor named in IRAS, but it does not need to be the same as the global Sponsor named in the protocol. The UK Sponsor could be contracted by the global Sponsor.

3.6.1 Whilst it is acknowledged that Legal Representatives must be appointed for CTIMPs sponsored by organisations not established in the UK (or otherwise not established in a country listed under regulation 3(11A) of the Medicines for Human Use (Clinical Trials) Regulations 2004 (specifically, as amended by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019)), the Sponsor(s) should still be Party to the Agreement. Their Legal Representative is not a Party to the Agreement, by virtue alone of being their Legal Representative.

3.6.2 Sponsors may formally empower another organisation to sign the Agreement on its / their behalf, thereby binding the Sponsor as a Party to the Agreement, as if it had itself signed. Evidence of such delegation of authority should be provided in the IRAS submission and appended to the Agreement in Schedule 6. The delegation of authority must explicitly state that the Sponsor allows the other organisation to sign agreements with sites on its behalf. Other activities such as negotiating contracts do not explicitly include entering into the agreement with the Trial Site on the Sponsor's behalf, and will not be accepted as sufficient evidence where they are present without this.

4. Principal Investigator

4.1 The Principal Investigator is not a Party to the mNCA. Optionally, Sponsors may choose to use the Schedule 5 Principal Investigator Declaration in mNCA. Use of this schedule does not make the PI party to the Agreement.

4.2 The Principal Investigator for the Trial Site will usually be employed by the Trial Site (or be a partner in the practice, as may be the case in an independent NHS contractor general practice Trial Site). This will not always be the case; for example, a PI at an NHS organisation who is a clinical academic substantively employed by a university. Where the Trial Site does not employ the Principal Investigator, or where the Principal Investigator is not a partner at the Trial Site practice:

4.2.1 Where appropriate[2], an honorary research contract should be put in place between the university employee and the NHS Organisation;

4.2.2 There should be clear understanding between Trial Site and employer of the PI as to their respective responsibilities and liabilities.

4.3 The Trial Site must ensure that the Principal Investigator's employer is aware of the involvement of their employee in the Study well in advance of the research commencing, and ideally of the mNCA being signed.

4.4 The mNCA should NOT be altered to become a tripartite agreement between Sponsor, Trial Site and a third party (for example the university substantive employer of the PI, a university providing other staff or facilities to the Trial Site, or a third party funding the Study). mNCA is a two party agreement, except for when the study is jointly or co-sponsored.

4.5 Where a hub and spoke agreement is used between the Trial Site and the Other Trial Site, schedule 2 should detail the arrangements to ensure that the PI effectively delegates and maintains oversight of the activities specified in schedule 2. Whilst it may be the case that the PI from the Trial Site should be given a Letter of Access to the Other Trial Site (where NHS), if their role foreseeably requires access in accordance with the HR Good Practice Resource Pack, this

[2] Refer to the HR Good Practice Resource pack: (https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx).

requirement is not automatic (no more so than any such requirement automatically applies to Chief Investigators).

5. Investigator Sites, Trial Sites and Hub and Spoke Agreements

5.1 The mNCA takes account of and aligns with UK guidance on the set up of research activity at NHS organisations (interventional research). Accordingly, the Party contracted by the Sponsor to conduct the Study is defined as the Trial Site.

5.2 The above referenced set-up guidance defines a Trial Site as "a legal entity responsible for some element of an interventional research study for which PI oversight is required". It also clarifies that one PI may oversee more than one Trial Site, or that one Trial Site may need more than one PI to ensure effective oversight.

5.3 The guidance (and the mNCA) uses the term Investigator Site for "the activities (regardless of their location) with effective oversight by one Principal Investigator".

5.4 A research study may therefore be delivered with one (or a combination of) the following PI oversight arrangements:

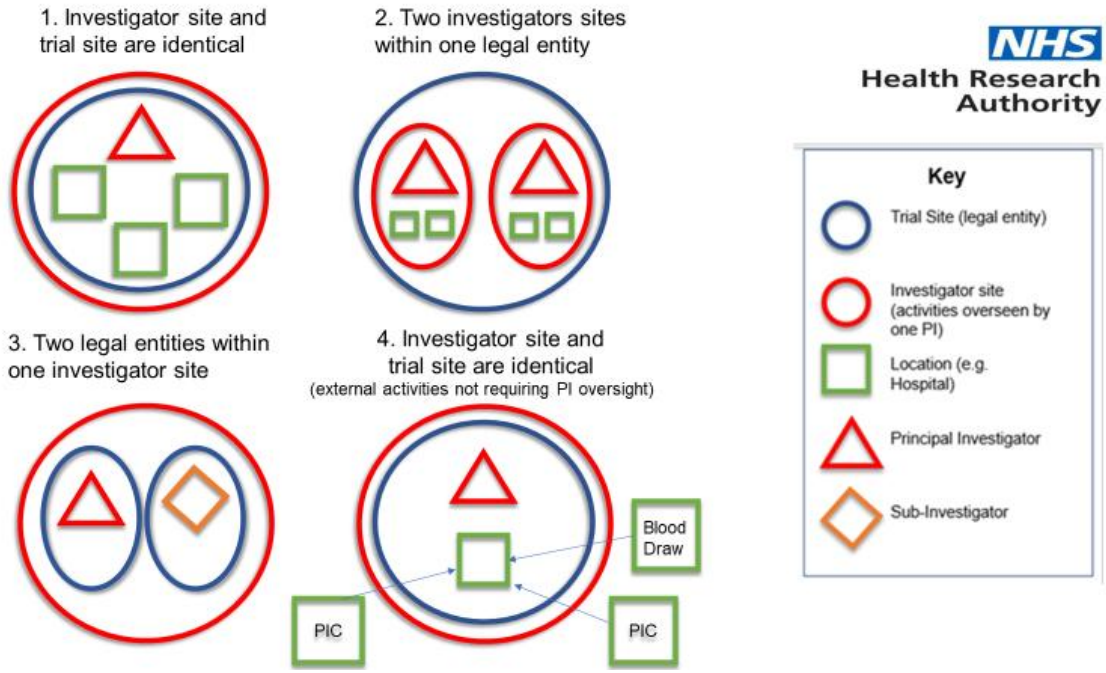
5.4.1 One Investigator Site per Trial Site. That is to say that there is one PI overseeing research activity at one legal entity (see figure 1.1), or;

5.4.2 More than one Investigator Site within the one Trial Site. That is to say that there is more than one PI for research activity occurring within the one legal entity, each PI having oversight for specific activities within that entity (see figure 1.2), or;

5.4.3 More than one Trial Site within the one Investigator Site. That is to say that one PI oversees research activities occurring within more than one legal entity (see figure 1.3);

5.4.4 There may also be other legal entities involved in the Study that are undertaking activities not needing PI oversight, for example general practices undertaking simple blood draws, Participant Identification Centres and so on (see figure 1.4).

5.4.5 **FIGURES 1.1 – 1.4**



5.5 Where there is more than one Investigator Site within the one Trial Site, one mNCA per Investigator Site should be agreed between the Parties. Whilst this means that the same Trial Site has more than one contract for the same Study, each contract would cover the activities specifically contracted to be overseen by one PI. Clause 11.2 has been updated to facilitate this approach. mNCA should not be altered to attempt to use one contract to cover more than one Investigator Site within the same Trial Site.

5.6 Where there is more than one Trial Site within the one Investigator Site, the mNCA has been drafted to allow the Lead Trial Site (that which employs the PI) to contract with the Sponsor using the mNCA. The Lead Trial Site then subcontracts to Other Trial Sites the aspects of the Study that they will conduct, overseen by the Lead Trial Site PI. A non-commercial hub and spoke template has been published for use alongside the mNCA in such circumstances, allowing the Lead Trial Site to subcontract with Other Trial Sites in a consistent manner.

Terms and Conditions

6. Definitions

6.1 **Sub-Investigator**: The definition of a Sub-Investigator is taken from ICH-GCP E6 R3. Sub-Investigators may perform activities on behalf of the Principal Investigator once delegated to them, as appropriate. This includes making important Study-related decisions and carrying out significant Study-related procedures. These decisions and activities could include confirmation of eligibility against the Protocol where this is unclear to the person screening the potential Participant, or standing in temporarily during short periods of absence by the Principal Investigator. Where activities are undertaken by a Sub-Investigator (or other Personnel), these remain the responsibility of the Principal Investigator, and appropriate oversight should be in place.

7. Legal and regulatory framework

7.1 In this section of the guidance the approach has been to elaborate on the rationale adopted in the agreement rather than to give a detailed legal explanation of the terms and conditions.

7.2 Health and social care research is a highly regulated field and it is key when carrying out research to understand the legislative regime that applies to that particular research project.

7.3 Clause 2.1 of the Agreement sets out the key laws, regulations and codes of practice that may apply to particular types of research. The list cannot and is not intended to be exhaustive, nor is each item necessarily applicable to all research. References to laws, etc. that are not applicable to a particular Study should not be removed from clause 2.1, nor should other laws, etc. be added. Proposals to make the Trial Site subject to foreign law will be rejected. It will be for each party in each case to ensure they, and as applicable their agents, are aware of all current law applicable to their Study.

7.4 More advice as to the relevant legislation can be found on the following organisation's websites:

7.4.1 The Medicines and Healthcare products Regulatory Agency, see http://www.mhra.gov.uk;

7.4.2 The Human Tissue Authority, see http://www.hta.gov.uk/;

7.4.3 The Human Fertilisation and Embryology Authority, see http://www.hfea.gov.uk/.

7.4.4 There is a raft of other legislation which will also apply. Some will apply for any study, such as health and safety and employment law, others will apply depending on the nature of the Study, such as if hazardous material or genetically modified organisms are used.

7.5 Clause 2.1 references the carrying out of the Study in accordance with the World Medical Association Declaration of Helsinki. The Declaration is a set of core ethical principles that apply to the carrying out of healthcare research.

7.5.1 Sponsors of CTIMPs must follow the principles of the 1964 Declaration of Helsinki, in line with the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. Sponsors may choose to only follow the principles of the 1964 Declaration, and not to place any further obligations upon themselves or Trial Sites. Two options are presented for the Sponsor to choose whether and how it will follow a full version of the Declaration of Helsinki in addition to the legal requirement. The Sponsor should delete both of these options if it will only follow the principles in the 1964 Declaration of Helsinki, or if it will expect a full version of the Declaration of Helsinki to be followed it should delete the non-applicable version.

7.5.2 Sponsors of non-CTIMPs have the option to choose which version of the Declaration of Helsinki to follow. One of these options should be chosen.

7.5.3 The 1996 Declaration of Helsinki was the version which was legally required to be followed for CTIMPs prior to the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. Sponsors may choose contractually to adhere to this version, whether they are conducting a CTIMP or not. It places no obligation on the Sponsor to make provision for any intervention to be provided to Participants post-Study.

7.5.4 The 2024 Declaration of Helsinki is the most recent version and therefore contains the most up to date global ethical expectations. Including this version in the Agreement places a contractual obligation on Sponsors to continue to provide an intervention to Participants post-Study where this is found to be "beneficial and reasonably safe" unless the ethics committee agrees to waive this requirement.

7.6 Respective Parties to the mNCA may have certain obligations arising from guidance relevant to their sector or terms of reference with funders. It will be for that Party to ensure that they comply with any such guidance or terms of reference. As compliance with the UK Policy Framework for Health and Social Care is key to healthcare research, it is a specific contractual obligation that all Parties to the mNCA comply with this.

7.7 Depending on the nature of the Study, approval must be obtained from one or more body before the research can commence. Responsibility to apply for such approval(s) is detailed in Schedule 2 and at Clause 2.2.2 there is an obligation on all Parties to conduct the Study in accordance with the relevant approvals.

7.8 Clause 2.9 requires the Principal Investigator to have reviewed any modifications to the Protocol which impact the conduct of the Study at the Trial Site, and to have confirmed that they and the Personnel can implement the modifications. This ensures that the Principal Investigator understands the requirements of the Study and can provide effective oversight. The review and confirmation provided by the Principal Investigator needs to be auditable, and should be proportionate in relation to the modifications. Examples of the auditable trail can include a file note, minutes of meetings, or an email trail with the Sponsor or Trial Site's R&D office discussing the modification.

The review and confirmation by the Principal Investigator does not relieve the Trial Site of its overall obligations to ensure that the modification can be implemented at the Trial Site. The Trial Site, as the Party to the Agreement, is responsible for ensuring that the contract is varied (if applicable) in line with Clause 11 of the Agreement, and that the modification is implemented as soon as possible. It is expected that the Trial Site and Principal Investigator work together to ensure timely review and implementation of modifications.

7.9 Clause 2.10.1 is mandatory for use where the Study is a Phase I CTIMP. It sets out obligations in relation adverse event reporting to facilitate the use of the mNCA for Phase I CTIMPs in NHS patients or healthy volunteers under NHS care. If the Study is not a Phase I CTIMP, this Clause should be deleted.

7.10 Clause 2.10.2 is mandatory for use where the Study is a Phase I dose escalation CTIMP in NHS patients or healthy volunteers under NHS care. It sets out obligations in relation to adverse event reporting. If the Study is not a Phase I dose escalation CTIMP, this Clause should be deleted.

7.11 The mNCA includes two clauses to describe the transparency arrangements for the Study, only one of which will take effect depending on whether the Study is a CTIMP (Clause 2.13) or a non-CTIMP (Clause 2.14).

7.11.1 Clause 2.13.5 includes three optional sub-clauses to reflect that a deferral to the Transparency Requirements has not been requested or issued (option 1), a deferral has been issued for all of the Transparency Requirements (option 2) or a deferral has been issued for only the publication of results and provision of a lay summary (option 3). Options 2 and 3 include sub-options to specify how the deferral is provided to the Sponsor. Where the deferral is provided to the Sponsor by email, this should be included in Schedule 7. Sponsors of CTIMPs should choose one option and delete the rest. Sponsors of non-CTIMPs should delete all three options.

7.11.2 Clause 2.14.1.b includes two optional sub-clauses to reflect that a deferral of registration has not been requested or issued (option 1) or a deferral of registration has been issued. Where a deferral of registration is issued, this should be included in Schedule 7. Sponsors of non-CTIMPs should choose one option and delete the other. Sponsors of CTIMPs should delete both options.

7.12 Clause 2.15 sets out the Retention Period and management of Study records after the Study has ended. Sponsors of CTIMPs must ensure that the editable sections of this clause in yellow highlight align with the requirements of the Medicines for Human Use (Clinical Trial) Regulations 2004 (as amended), and in particular that Clauses 2.15.1.a and 2.15.1.b are retained. Clause 2.15.2 clarifies the management of Study record destruction in line with the Medicines for Human Use (Clinical Trial) Regulations 2004 and / or Sponsor instruction, as appropriate to the Study. Clause 2.15.2.a allows the Trial Site to destroy Study records where the Retention Period has expired and it has asked the Sponsor to destroy the records but has not received a response within the contractual timeframe. This position is in line with guidance received from the MHRA for CTIMPs, and has therefore been aligned for non-CTIMPs.

8. Liability

8.1 Liability may arise during a research project in a variety of ways. Given the complexities of this area we explain this below and how Clause 3 apportions responsibility between the Parties.

9. Negligence

9.1 Liability for clinical negligence on the part of Trial Site staff conducting research, including a Principal Investigator engaged under an honorary research contract, lies with the Trial Site. An NHS Organisation will be indemnified for such clinical negligence by the appropriate risk sharing scheme provided, for England and Wales, HRA and HCRW Approval is in place and its conditions on confirmation of capacity and capability followed or, in Scotland, management permission is in place or, in Northern Ireland, the Trial Site has confirmed that the Study may commence by provision of signed contract.

10. Non-Negligent Harm

10.1 The NHS risk sharing schemes do not give an indemnity for compensation in the event that a Participant is harmed and no one is at fault, for example an unexpected side effect from the administration of a drug.

10.2 NHS Organisations and some other public bodies cannot offer to compensate Participants in these circumstances in advance of any harm occurring. Nor can they take out commercial insurance for non-negligent harm (NHS Foundation Trusts may take out such insurance). Any such payment, called an ex gratia payment, can only be considered at the time the harm occurs.

10.3 Research Ethics Committees consider whether there is adequate compensation for the project in question. Occasionally, the Research Ethics Committee may decide that there is a need for no-fault compensation. As NHS organisations and certain other public bodies cannot agree to this in advance, the Study will only receive a favourable opinion if a Sponsor that is able to do so is willing to provide insurance for non-negligent harm.

11. Other Forms of Loss and Damage

11.1 Liability can arise in a variety of other ways. For example:

11.1.1 The drug being trialled or the research methodology could infringe a third party's intellectual property rights and the Parties to the Agreement could be sued for such infringement; or

11.1.2 As part of the Study, if it is necessary to assemble or prepare equipment or medicines and if the equipment or medicine is faulty and causes harm, then liability could arise for the organisation doing such assembly or preparation under product liability law; or

11.1.3 The Study may use third party confidential information which is breached and the third party seeks to recover any loss they suffer.

12. Clause 3 provisions

12.1 This clause seeks to apportion liability between the Parties for the main forms of loss and damage that could arise under the Agreement as follows:

12.1.1 Clause 3.1 states the general legal position regarding statutory or regulatory liability, death and personal injury arising from negligence or wilful misconduct.

12.1.2 Clause 3.2 deals with the insurance (or equivalent indemnity) each Party shall have and evidence as having to cover their respective liabilities under the Agreement.

12.1.3 Clause 3.3 provides for a single Sponsor, Joint-Sponsor or Co-Sponsors. The relevant version of the clause should be selected and the other two deleted. Clause 3.3 provides Sponsor indemnity to the Trial Site for any Claims arising from the Sponsor's (or their Agent's) wilful misconduct and / or their negligent acts or omissions. This includes misconduct and / or negligence in the design and / or management of the Study (i.e. the

Sponsor is responsible for the Protocol and indemnifies the Trial Site against claims arising from the Protocol being followed). However, the scope of the indemnity is limited. The Trial Site does not get the benefit of the indemnity if the claim resulted from treatment or a procedure which is routinely undertaken as part of medical treatment at the Trial Site, or if the loss arose from negligence or breach of statutory duty of the Trial Site. The indemnity does not apply if both the Sponsor and the Trial Site are NHS organisations, as NHS organisations cannot, as a general rule, indemnify one another (see Clauses 3.9 to 3.12).

12.1.4 Clauses 3.9 to 3.12 address respective liability where both Sponsor and Participating Organisation are NHS organisations.

12.1.5 Clause 3.10 addresses circumstances where both Parties are members of the same risk sharing scheme and the loss is covered by that scheme. Where legal liability rests is, in these circumstances, a matter for the relevant risk sharing scheme to consider and it will determine how to apportion financial liability. This clause reflects the practice of the risk sharing scheme.

12.1.6 Clause 3.11 addresses circumstances where the Parties are NHS organisations in Scotland, as different rules apply; where the Parties are NHS organisations in different UK nations; and where the Parties are members of the same risk pooling scheme and the loss is not covered by the schemes. In any one of these circumstances the parties will need to reach agreement on respective responsibility for the loss. If they cannot do so, as the Agreement is not enforceable by a court, it must be resolved in accordance with Clause 15.5.

12.1.7 Clause 3.12 addresses the case where one or more of the parties is an NHS Foundation Trust and the party incurring a loss is not itself covered for that loss by one of the NHS schemes.

12.1.8 Clause 3.13 caps the contractual liabilities of the parties.

12.1.9 Clause 3.14 constrains the liability of the Trial Site in relation to loaned or gifted equipment.

12.1.10 Clause 3.15 is for use at the option of non-NHS sponsors, to be used where such sponsors choose to offer no-fault compensation to study participants who may be harmed as a result of their participation.

13. Confidentiality, Data Protection and Freedom of Information

13.1 All Parties will be bound by legal obligations of confidentiality in respect of Participants and potential Participants. This applies to confidential patient information under the common law as well as Personal Data under GDPR and Data Protection Act 2018.

13.2 The Data Processing terms have been drafted in accordance with GDPR and the Data Protection Act 2018. They recognise the identity of Sponsor as data controller and of Trial Site as data processor (for the personal data processed for the purpose of the Study) and ensure that the processor is legally bound as required by GDPR Article 28 (3).

13.3 Clauses 4.1.8.b and 4.1.9 relate to the Trial Site processing personal data for the purpose of the Study outside of the UK and the EEA. This may be the case where the Trial Site relies upon cloud-based storage, or similar arrangements. Such arrangements should be disclosed by the Trial Site to the Sponsor in advance of executing the Agreement and, where such arrangements are introduced subsequent to Agreement execution, the agreement of the Sponsor should be obtained. The responsibility of the Trial Site to ensure that such arrangements are legally compliant is noted at 4.1.9.

13.4 The Data Sharing Terms are no longer optional clauses, as they are now designed to safeguard not only personal data leaving the NHS but also to safeguard data that has been rendered no longer personal data to the recipient (for example, to place obligations on the sponsor and its agents to not attempt to re-identify data that has been pseudonymised).

13.5 Under the mNCA the Trial Site must treat the Results (excluding its own Clinical Data) as Confidential Information. The reason for this is to protect the Sponsor should a funder have required such a provision in its arrangements with the Sponsor.

14. Publicity

14.1 Clause 5.1 of the Agreement requires the approval of the other Party to the Agreement to use their name, logo or a registered image (or that of their Agent(s)) in any publicity, press release or advertising. Clause 5.2 requires that the timing and content of publicity and advertising shall be agreed between the Parties. This provision is not intended and should not be construed as placing any proscription on NHS bodies fulfilling obligations to publish information on studies in which they are participating, nor on sponsors fulfilling similar obligations.

15. Publication

15.1 The UK Policy Framework for Health and Social Care sets out the responsibility of the Sponsor to make available the findings of research, thus placing research Sponsors under a responsibility to publish the Results of research projects. Additionally, CTIMPs are subject to the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 which requires Sponsors to publish the Results on a Public Registry. Clause 6.1 imposes an obligation on the Sponsor to publish the Results in line with the policy and / or legal requirements applicable to the Study, subject to the conditions of any deferral in place.

16. Intellectual Property

16.1 The drafting of the intellectual property clauses, like the rest of the mNCA, reflects the desire to be as user friendly as possible. However, the principles underlying the clauses are somewhat complex and have been explained in full here.

17. Ownership

17.1 The principles in the mNCA around ownership of intellectual property and Know-How are as follows:

17.1.1 Each Party retains ownership of any intellectual property or Know-How they owned prior to the start of the Study.

17.1.2 All intellectual property and Know-How in the Protocol, Results or otherwise arising directly from the Study is owned by the Sponsor, Joint-Sponsors or one or both Co-Sponsors where there is more than one Sponsor. It is for the Co-Sponsors to address any ownership issues as between themselves. The reasoning behind ownership by the Sponsor is that it is anticipated that very little intellectual property will be generated by the Trial Site carrying out the Study. The mNCA is not for use where the Trial Site is a joint or co-sponsor. If the Trial Site has contributed to the design of the Study and will therefore own or otherwise be a beneficiary of arising IPR, this should be dealt with not by altering the mNCA but by separate contract apportioning those rights from Sponsor to Trial Site. Similarly, if during a Study those carrying out the research start to contribute in an innovative manner, for example by suggesting changes to the structure or methodology of the Study, the Parties may need to consider dealing with intellectual property issues by separate but additional agreement. At such time it is relevant to consider the extent of this contribution, who should own the intellectual property rights in it, how the Trial Site may wish to use the contribution in the future and whether, should the Sponsor proceed either itself or through a third party to commercialise the Results, if the contribution is such that the Trial Site should share in the reward of this.

17.2 However, it is envisaged that these circumstances arising will be by exception and that the role of the Trial Site is to carry out research for a Study that has been developed by the Sponsor and the research will be carried out in the manner directed by the Sponsor. Therefore, very little, if any, independent work will be carried out by the Trial Site.

17.3 The Sponsor only owns intellectual property created directly through the Study. If the Trial Site develops clinical procedures that are only indirectly related to the Study, the Trial Site keeps the rights to those. However, the Trial Site may not be able to use them if they rely on the Sponsor's existing intellectual property.

17.4 There may be instances where the Sponsor is assigned Intellectual Property Rights under this Agreement but it is not the actual owner of the assigned Intellectual Property. This can happen in situations such as:

- If a **Funder agreement** states that the Funder owns the new Intellectual Property created during the Study
- If a **pharmaceutical company** providing a study drug owns any Intellectual Property that results from using their drug
- If a **student** involved in the Study owns the Intellectual Property they personally create

In these cases, the Sponsor may be assigned or asked to manage certain Intellectual Property rights for practical reasons, but the actual ownership belongs to another party. Because of this, if the Sponsor is not the actual owner of the Intellectual Property being assigned to it in this Agreement, the correct ownership arrangements should be clearly set out in a **separate background agreement** between the Sponsor and the relevant party - not by changing the mNCA itself.

18. Use of Intellectual Property Rights

18.1 One Party may use another Party's pre-existing intellectual property rights in carrying out the research.

18.2 Clause 7.5 allows the Trial Site to use Study Data that is Clinical Data (at its own risk) in the provision of clinical care (providing that this does not result in disclosure or misuse of the information or infringement of the IPR). Clause 7.6 requires the Trial Site to obtain prior written permission from the Sponsor should it wish to use any Study Data (at its own risk) for normal activities outside of clinical care (e.g. commissioning, teaching or research).

19. Governing law

19.1 The conduct of the Study at the Trial Site is governed by and subject to the law applicable to the Trial Site (clause 18.1). For any other issue concerning the agreement, the governing law and court with jurisdiction over the Agreement (Clause 18.2) is that of the UK country in which the Sponsor is established. This can be overridden at the election of the Parties and any such change must be in writing. Where the Sponsor is not established in the UK, a different version of clause 18.2 is provided whereby the governing law is that of the UK nation in which the Trial Site is established. The relevant clause 18.2 should be retained and the other deleted prior to the Sponsor sharing the agreement with the Trial Site.

Template Schedules

Each of the Schedules will need completing for each and every research project.

20. Schedule 1 – Study Support Arrangements

20.1 Schedule 1 provides for key information to be inserted regarding details of organisations and individuals involved in the Study, as well as numbers of Participants and samples required for the Study at the Trial Site.

20.2 Where applicable, Schedule 1 provides for Other Trial Sites, to which the Trial Site has subcontracted activities to be overseen by the PI, to be listed in accordance with Clause 2.3.

20.3 Schedule 1 also provides for the contact details of the Parties to which Notices should be addressed.

21. Schedule 2 – Study Conduct at the Trial Site DIVISION OF RESPONSIBILITIES and DELEGATION OF ACTIVITIES

21.1 The aim of this Schedule is to record key respective responsibilities and any delegation of activities associated with these responsibilities. The template is not intended to be an exhaustive list and will vary from project to project.

21.2 The Sponsor should set out the division of responsibilities and delegation of activities in the table contained in the Schedule. Those responsibilities grouped in the first eight clauses will apply to all research projects. There are then specific responsibilities for a clinical trial and studies involving medical devices. Where a particular responsibility is not applicable to the Study, “not applicable” should be entered in the column designating “Responsible Party”. Space is left for additional responsibilities. This may be relevant when, for example, a study involves tissue samples or material transfer.

21.3 Where there are Co-Sponsors, the name of the Sponsor responsible for each activity should be given (Joint-Sponsors are jointly responsible for all Sponsor responsibilities).

21.4 Sponsor and Trial Site should not be named as jointly responsible for any one responsibility. Their respective responsibility shall be as laid down in applicable legislation, guidance and the governance arrangements for the Study or as is otherwise applicable to their respective roles in the Study. Whilst responsibilities are non-delegable, activities related to responsibilities may be delegated and should be recorded as such in Schedule 2.

21.5 Where the Trial Site is subcontracting research activities to another Trial Site within the Investigator Site, or otherwise delegating activities, the detail of what is delegated to whom should be recorded here and updated by contract variation as applicable.

21.6 It is intended that all capitalised terms used in this Schedule but not otherwise defined in the Agreement should been interpreted in accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended.

22. Schedule 3 Study Support Arrangements

22.1 This Schedule covers a number of important elements as follows:

22.2 It provides for the financial arrangements for the Study – how much is payable, when it is paid (and this may be linked to the achievement or milestones, or on specific dates) and the manner of payment.

22.3 The costs paid by the Sponsor and contained in the Schedule may typically include, but are not limited to, the costs of:

22.3.1 Screening;

22.3.2 Visits;

22.3.3 Provision of pharmaceuticals; and

22.3.4 Use of diagnostic tools.

22.4 When setting up the Study it will be important for the Trial Site to consider all financial issues and ensure recovery of full NHS costs associated with carrying out the research[3]. These may also include:

22.4.1 Staff costs including administrative staff and costs of staff employed under an honorary research contract;

22.4.2 Services costs such as clinics, bed days, imaging, pharmacy costs;

22.4.3 Administrative costs and other overheads;

22.4.4 Travel and related expenses.

22.5 The Schedule addresses the possibility of items being provided to the Trial Site by the Sponsor or a third party or obtained by the Trial Site for use in the Study. These items could be medicine, equipment, software or other materials. Depending on the nature of the item, it will be important to make clear who is responsible for obtaining and paying for any such items, who owns them, insurance and storage arrangements, training and maintenance of the items and what happens to them at the end of the Study.

22.6 Where the study involves the Trial Site subcontracting activities to Other Trial Sites, or otherwise delegating activities to other third parties, the arrangements by which the Sponsor pays, or otherwise makes provision for, these activities to the Trial Site, would usually be set out here. The arrangements by which the Trial Site pays, or otherwise makes provision, for these activities, to the Other Trial Site(s) will be set out in relevant subcontracts, or similar.

23. Schedule 4 Material Transfer Provisions

23.1 If this Schedule does not apply, the box should be checked.

24. Schedule 5 Principal Investigator Declaration

24.1 If this Schedule does not apply, the box should be checked.

24.2 Alternatively, where this Schedule will be used it should be signed by the Principal Investigator and the box remains unchecked.

25. Schedule 6 Formal Delegation of Authority to Another Party to Contractually Bind Sponsor

25.1 If this Schedule does not apply, the box should be checked.

25.2 Alternatively, where this Schedule will be used the document which confirms the Sponsor is delegating its authority to another organisation to enter into the agreement on its behalf and contractually bind it to its terms should be appended

[3] NHS Organisations should cost in accordance with appropriate guidance, such as the NHS Finance Manual and cost recovery should be in accordance with the principles set out in AcoRD.

here. The delegation of authority must explicitly state that the Sponsor allows the other organisation to sign agreements with sites on the Sponsor's behalf. Other activities such as negotiating contracts do not explicitly include entering into the agreement with the Trial Site on the Sponsor's behalf, and will not be accepted as sufficient evidence where they are present without this.

26. Schedule 7 Authority to Defer the Transparency Requirements for the Study

26.1 Where there is no deferral in place to defer the transparency requirements, in line with Clause 2.13 or Clause 2.14 (as applicable), check the box to indicate this Schedule does not apply. Where there is a deferral in place for a CTIMP and this is contained within the research ethics committee's favourable opinion letter, the box should also be checked as this Schedule does not apply.

26.2 Otherwise, where a deferral is in place and this has been provided to the Sponsor by email, this should be appended here.

Development and Maintenance of the mNCA and Change History

27. Development of the mNCA

27.1 The first UK model Agreement for Non-Commercial Research (mNCA) was drawn up and published in 2008. It followed on from the 2003 publication of the model Clinical Trial Agreement (mCTA) for pharmaceutical (commercial) research and shared the same intention; of providing a standard template to document agreement between the Parties (as per 1.1) that does not require further legal review or negotiation and hence results in a more straightforward and efficient study set-up process.

27.2 mNCA 2008 was developed through three rounds of consultation, including input from UKCRC, the Medical Schools Council (MSC), the NHS R&D Forum, the Medical Research Council (MRC), the UK Health Departments and representatives from universities and research networks. Prior to publication the document was legally reviewed.

27.3 Although uptake of mNCA 2008 was high amongst NHS Sponsors, many university Sponsors felt unable to use the template in an unaltered form. In 2013, work undertaken by the UK Clinical Research Collaboration Registered Clinical Trials Units (UKCRC CTUs) identified, amongst others, the following reasons for this:

27.3.1 Indemnity and liability clauses not appropriate to University Sponsors

27.3.2 Lack of reciprocal indemnity

27.3.3 Inability to reflect terms and conditions of third-party funding agreements

27.3.4 Co-Sponsor and Joint-Sponsor arrangements not adequately reflected

27.3.5 Lack of material transfer clauses and other additional obligations on the Parties

27.4 In 2014 the Health Research Authority (HRA) agreed to work with the UKCRC CTUs to develop a revised mNCA to address these issues. There followed a number of rounds of consultation, including a formal open call for comment across all four UK nations in 2015 and an all-stakeholder engagement event to review these comments. In October 2017 the draft IG clauses were reworked explicitly to take account of the forthcoming General Data Protection Regulations and Data Protection Act (Data Protection Legislation) and further iterations led to the version put to lawyers in England by the HRA, and equivalent reviews in Scotland, Wales and Northern Ireland, in June 2018. Following these reviews, version 2.0 was launched at an all-stakeholder event in June 2018 and, taking account of feedback from this event, version 2.1 was published in July 2018.

27.5 In January 2021 the Four Nations UK Contracting Leads Group agreed and published version 2.2, with minor revisions made primarily to align the template with the legal situation following the exit of the UK from the EU. Additional minor changes were made as a result of suggestions made since publication of the 2018 version.

27.6 In July 2022 the Four Nations UK Contracting Leads Group agreed and published version 2.3, with minor revisions made primarily to allow the template to form a head agreement between sponsor and lead trial site, from which the lead trial site may subcontract to other trial sites overseen by the PI of the lead trial site. These changes follow from publication of UK guidance on the set up of research activity at NHS organisations (interventional research). Additional minor changes were made as a result of other developments, feedback following publication of the 2021 version and comments on drafts of the 2022 version from representatives of sponsors, CTUs and sites.

27.7 In July 2022 the Four Nations UK Contracting Leads Group agreed and published the first UK template non-commercial hub and spoke agreement, designed to be used by Trial Sites to subcontract to Other Trial Sites activities overseen by their PI. Where applicable, the mNCA and non-commercial hub and spoke agreement have been drafted to function together as head agreement and subcontract.

27.8 Version 3.0, April 2026 of the mNCA was introduced to accommodate changes needed as a result of the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. Further updates were made to account for policy changes applicable to clinical trials which are not of an investigational medicinal product. Additionally, changes were made for consistency with the commercial clinical trial agreements to align with changes made since the 2022 mNCA, and to address feedback received since that version was published.

28. Maintaining the mNCA Template

28.1 To ensure that the mNCA remains current in a changing regulatory environment and to take all advantage of expert experience in its use, the UK Four Nations Contracting Leads group meets regularly and considers proposals for updates to the template. Suggestions for updates to the template (and/or this guidance document) should be e-mailed as per contacts provided below.

For queries relating to the use of the mNCA for studies taking place in England:
please contact the Health Research Authority, at research.agreements@hra.nhs.uk.

For queries relating to use in Wales:
please contact the Health and Care Research Wales Support and Delivery Centre at research-contracts@wales.nhs.uk.

For queries relating to use in Scotland:
please contact NHS Research Scotland at enquiries@nrs.org.uk.

For queries relating to use in Northern Ireland:
please contact ResearchContracts@innovations.hscni.net.

29. Change History

April 2026 Version

29.1 This version brings in changes to align with the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 for Studies which are clinical trials of investigational medicinal products (CTIMPs). It also brings in changes which reflect associated policy updates regarding the management of Studies which are not CTIMPs.

29.1.1 Updated terminology throughout: Study “amendments” referred to as “modifications” to align with legislation; contract “modifications” referred to as “variations”

29.1.2 Addition of the following definitions: Authority, Clinical Trial Approval, Public Registry, Retention Period, Study Completion, Sub-Investigator, Transparency Requirements.

29.1.3 Clarification in Clause 1.2 that the version of the Declaration of Helsinki which is published is the only version which will apply to the contract.

29.1.4 Update to Clause 2.1.12 forthe reference to Declaration of Helsinki to clarify either adherence to the legal minimum requirement, or to specify the full version of the Declaration of Helsinki they will follow.

29.1.5 Addition of Clauses 2.4, 2.9 and 2.10 to align with equivalent clauses for commercial trials and to clarify expectations raised by the MHRA in ensuring compliance with the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) and GCP.

29.1.6 Addition of Clauses 2.13 (CTIMPs) and 2.14 (all other clinical trials) to set out transparency expectations under the legislation or policy, and associated update to Clause 17 (Survival of Clauses).

29.1.7 Addition of Clause 2.15 to clarify record retention and archiving requirements, in line with the commercial agreements, and to specify archiving requirements for CTIMPs under relevant legislation, and associated updates to Clause 17 (Survival of Clauses) and Schedule 2 Clause 8.

29.1.8 Addition in Clause 6.1 of an obligation for Sponsors of CTIMPs to adhere to publication obligations referred to in Clause 2.13, and for Sponsors of

non-CTIMPs to adhere to expectations regarding publication when they have a deferral in place.

29.1.9 Addition of responsibilities regarding transparency requirements for CTIMPs in Schedule 2 Clause 9.

29.1.10 Addition of a warranty in Schedule 3 Part B that any medicines, equipment, consumables, software or other items used in the Study shall be fit for their intended use.

29.2 Other changes are brought in to align with agreed changes to the commercial agreements which have been made over the last four years. This ensures consistency of expectations for Sponsors and Trial Sites and continuing adherence to legal requirements.

29.2.1 Addition of three new optional recitals and an option contact point for notices in Schedule 1 for use where the Study is a clinical investigation of a medical device and the Trial Site is in Northern Ireland to state a legal representative or contact person, as appropriate to the Study.

29.2.2 Updates made to the following definitions: Agent, Agreement, Confidential Information, Data Protection Laws and Guidance, Lead Trial Site, Other Trial Site(s), Principal Investigator.

29.2.3 Update to the name of the defined term Data Protection Legislation to Data Protection Laws and Guidance.

29.2.4 Addition of the definition Personal Data Breach.

29.2.5 Addition of Clause 1.3 to specify that NHS includes HSC if the Trial Site is in Northern Ireland.

29.2.6 Update to Clause 2.11 to clarify anti-bribery and corruption requirements.

29.2.7 Addition of Clause 2.12 to provide a contractual obligation for the Parties to update contact details, including for notices and payment, and associated update to Clause 17 (Survival of Clauses).

29.2.8 Addition of Clause 4.1.6.l to clarify the management of Personal Data Breaches in line with GDPR.

29.2.9 Update to timelines through the document, where applicable, to refer to working days for consistency with the commercial agreements.

29.2.10 Check boxes to make Schedules 4 and 5 not applicable where they are not used, instead of being optional and removable.

29.3 Corrections and further changes are brought in line as a result of feedback received since the 2022 version was published, including alignment with changes made to the April 2026 commercial agreements, ensuring consistency of expectations for Sponsors and Trial Sites.

29.3.1 Clarification that the Sponsor organisation is the organisation acting as Sponsor in the UK.

29.3.2 Addition of a new recital and Schedule 6, and update to the signature block to accommodate situations where the Sponsor has delegated authority to another organisation to enter into agreements with Trial Sites on its behalf.

29.3.3 Addition of a new definition and clarification in Clauses 11.2 and 16.1 regarding the relationship between the mNCA and any separate Collaboration Agreement between the Sponsor and Trial Site.

29.3.4 Addition of Clause 2.1.11 (adherence to the UKRI policies and principles Human Biological Samples)

29.3.5 Amendment of Clause 2.3, with the addition of Clause 2.3.1, to state Other Trial Sites agreed with the Sponsor prior to the start of the study.

29.3.6 Clarification in Clause 3.9 regarding the National Health Service (Scotland) Act 1978.

29.3.7 Clarification in Clause 4.1.2 that the Clause relates to the Trial Site's Processing of Personal Data.

29.3.8 Addition of Clause 4.1.6.j to clarify obligations under Article 28 of GDPR.

29.3.9 Clarification in Clause 4.1.11 that Sponsor will only use Personal Data or Pseudonymised Data supplied in line with the approved consent form.

29.3.10 Inclusion of the Environmental (Scotland) Regulations 2004 to relevant parts of Clause 4.2.

29.3.11 Clarification that Clause 4.3.2 applies to the Receiving Party's Agents, and not just to a set list of parties.

29.3.12 Update to the confidentiality obligation time limits in Clause 4.4.

29.3.13 Update to Clause 10, Termination, to align the commercial and non-commercial agreements more closely, and associated update to Clause 17 (Survival of Clauses).

29.3.14 Update to Clause 14.4 to clarify any sub-contractors are bound by contractual obligations at least as stringent as those in the mNCA.

29.3.15 Clarification in Clause 15.2.2 of the appropriate organisation in Northern Ireland to refer disputes between the Parties to.

29.3.16 Instructions updated throughout the agreement accordingly in line with changes made throughout.

29.3.17 Clarification in the instructions for Schedule 2 that the Chief Investigator does not need to be listed as a delegated party when they are employed by the Sponsor or Trial Site.

29.3.18 Clarification in Schedule 2, Clauses 6.b and 6.d where responsibility for coding Personal Data lies.

29.3.19 Replacement of BACS with bank transfer as a payment method in Schedule 3 to accommodate organisations paying which are based outside of the UK.

29.3.20 Addition of guidance in relevant places throughout the document.

Summary of alterations to previous versions

N.B. The below text is taken verbatim from previous versions of this guidance and is intended for reference purposes only. Changes referenced below may themselves have been superseded by subsequent changes.

2022 Version

29.4 Changes have been made to align with the guidance on setting up interventional research, specifically to align with the concepts of Investigator Site and Trial Site and to:

29.4.1 Allow for multiple agreements to be signed by the one Trial Site when it contains multiple Investigator Sites, and/or;

29.4.2 Allow the template to form a head agreement between Sponsor and Lead Trial Site, from which the Lead Trial Site may subcontract to Other Trial Sites overseen by the PI of the Trial Site.

29.5 These changes include:

29.5.1 Updated definition of the contracting body, from Participating Site to Trial Site;

29.5.2 New optional recital for use when the Lead Trial Site will be subcontracting with Other Trial Sites;

29.5.3 New definition of Investigator Site;

29.5.4 New definition of Lead Trial Site;

29.5.5 New definition of Multi-Centre;

29.5.6 New definition of Other Trial Site(s);

29.5.7 Removal of definition of Site;

29.5.8 Revised clause 2.3 with new optional wording for use when Trial Site is a Lead Trial Site within the Investigator Site;

29.5.9 Additional wording in clause 11.2 to allow for multiple Investigator Sites within the one Trial Site, without subsequent contracts superseding prior contracts;

29.5.10 Schedule 1 modified to allow for recording of details of Other Trial Sites, where applicable;

29.5.11 Schedule 2 modified to make explicit reference to recording delegation of activities to Other Trial Sites within the Investigator Site, where appliable.

29.6 Another key change is that the formerly optional data sharing terms are no longer optional but a standard part of the template, having been modified to cover sharing of Pseudonymised Data (as defined in the agreement) and/or Personal Data. As a result, the agreement includes a definition of Pseudonymised Data. This further aligns mNCA with mCTA.

29.7 Other changes include:

29.7.1 Definition of Data Protection Legislation revised following the EU decision on the adequate protection of Personal Data by the United Kingdom - General Data Protection Regulation;

29.7.2 Revised clause 2.1 (under clause 2, Obligations of the Parties), specifically to highlight key laws and codes of practice relevant to the roles and responsibilities of the Parties. The drafting aligns with that in mCTA;

29.7.3 Introduction, in various clauses, of the concept of 'potential' Participants, to ensure that (for example) data protection clauses act in relation to the data of persons identified as potential Participants, whether or not they subsequently become (actual) research Participants;

29.7.4 Inclusion of references to on-site or remote means of audit/monitoring in clauses 2.4 and 2.7;

29.7.5 New anti-bribery and corruption clauses at 2.8 and 2.9, aligned with mCTA;

29.7.6 Minor modifications throughout clause 3 to account for NHS Resolution's English Clinical Negligence scheme for General Practice (CNSGP);

29.7.7 Explicit reference added in clauses 3.6 and 3.7 to Agents;

29.7.8 Clarification in clause 3.13 that the liability arising from breach of Agreement is capped at, not automatically amounting to, £100K;

29.7.9 Clarification at clause 4.1.3. that controllership is related directly not necessarily to the purpose for which personal data is collected but the purpose for which it is processed, aligning with mCTA;

29.7.10 Clause 4.1.14(a) clarified in relation to access for purposes not incompatible with the purpose of research and not incompatible with the Participant consent;

29.7.11 Clarification at 4.3.3 as to the conditions under which clause 4.3.2 (in addition to clause 4.3.1) shall not apply;

29.7.12 Clarification at clause 5.1 that the prohibition is to publicity, etc. related to the agreement;

29.7.13 Clause 18.2 has been split into two variant clauses, to clarify arrangements when the sponsor is not established in the UK;

29.7.14 Reiteration at clause 19 that the signature block should appear on the same page as the last clause in the body of the Agreement;

29.7.15 Additional clauses in Schedule 3.

2021 Version

29.8 The template has been updated to reflect the legal situation following the departure of the UK from the EU, specifically:

29.8.1 Reference to EEA in the fifth recital replaced by reference to a country listed under regulation 3(11A) of the Medicines for Human Use (Clinical Trials) Regulations 2004 (specifically, as amended by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019);

29.8.2 Definition of Data Protection Legislation updated;

29.8.3 New definition of GDPR, made to specifically reference the UK GDPR;

29.8.4 Addition of "UK and the" at Clauses 4.1.8.b and 4.1.9, to reflect that the UK is outside of the EEA but that the UK continues to regard the countries within the EEA as having equivalent data protection regimes.

29.9 Additionally, the following non-BREXIT related minor revisions have been made, as a result of suggestions received following publication of the 2018 version:

29.9.1 Reference to the Legal Representative signing the Agreement has been removed, as this is not a Legal Representative responsibility (although it may be a responsibility additionally and formally delegated to the Legal Representative by the Sponsor. Where this is the case, evidence of this delegation should be provided in the IRAS submission);

29.9.2 The definition of CI has been amended to include reference to the individual named in Schedule 1;

29.9.3 Clause 2.4 has been added to reflect the responsibility on the Participating Site to use reasonable endeavours to recruit participants to the Study as agreed in Schedule 1;

29.9.4 Reference to the Environmental Information (Scotland) Regulations 2004 (EI(S)R) added to Clauses 4.2.1 and 4.3.3.g;

29.9.5 Clause 4.3.2.e added to clarify responsibility of the Parties treating as confidential any confidential information that comes to its knowledge as a result of a visit to the establishment of the other Party;

29.9.6 Clarification that Know-How referred to is Background Know-How added to clause 7.1;

29.9.7 Clarification added that IPR and Know-How referred to as being in the Protocol and belonging to the Sponsor includes other documents and information disclosed by the Sponsor;

29.9.8 Clause 16.5 added to clarify that the Agreement should not be construed as creating a joint venture, contract of employment or relationship of principal and agent between the Parties;

29.9.9 References to governing law and jurisdiction at Clauses 18.1 and 18.2 respectively corrected to reference “England and Wales” in place of “England/Wales”;

29.9.10 It has been clarified that Clause 18.2 is optional and should be deleted if not applicable;

29.9.11 Clause 5.4 or Schedule 4 has been deleted, as the obligation to not alter title, coding or acronym of Material is not appropriate in all cases.

2018 version

29.10 The key reasons given by Sponsors for not adopting the 2008 version are given at 1.4. The redrafting process initially sought to address these issues only but, over time and as a result of extensive stakeholder engagement and changes in background legislation, etc., the number of revisions grew substantially. These included, latterly, substantial revisions to take account of updated Data Protection Legislation. The below is a high-level summary of the key changes between the 2008 and 2018 versions:

29.10.1 The 2008 version was drafted for exclusive use with Participating Sites in the Health Services. By referencing Site and Participating Site in place of NHS Organisation (and in other ways) the 2018 version may function as a template for use with non-NHS Participating Sites;

29.10.2 Referencing Site and Participating Site allows the Agreement between the Sponsor and Participating Site (the legal entity, e.g. NHS Trust or Health

Board, signing as a Party to the Agreement on behalf of the Site) to cover multiple Sites where appropriate (e.g. to allow for the uncommon scenario where different hospitals within a single NHS organisation function as discrete investigator Sites). Additional Sites within the Participating Site may therefore be added by varying the Agreement (e.g. by appending additional Schedules 1, 2, 3, 4 and/or 5 as applicable);

29.10.3 The introduction of recitals allows for the Sponsor to provide context and clarity, without this additional useful information forming part of the Agreement or modifying the template in any way;

29.10.4 The definitions have been expanded upon and key definitions redrafted. The definitions clause also provides for references in the Agreement to statutory provisions, etc. to be deemed to refer to modifications and/or re-enactments thereof;

29.10.5 The Obligations of the Parties have been expanded upon, particularly in respect of auditing, monitoring, investigating, inspecting, etc. The Agreement provides the right for Sponsor personnel (and/or those of its Agents) to access the Participating Site to audit and/or monitor (the HR Good Practice Pack was not drafted to cover such activities and Honorary Research Contracts and Letters of Access are not appropriate tools or mechanisms to manage such access);

29.10.6 The Liabilities and Indemnities section introduces variant clauses to allow the template to reflect common single, Co- and Joint-Sponsor arrangements and takes account of the possibility of non-NHS Parties.

29.10.7 The 2018 version introduces reciprocal indemnity, with the Participating Site indemnifying the Sponsor and a monetary cap on liability (which serves to also, although not exclusively, cap the indemnity) has been introduced (£100,000, or amount payable under the Agreement, whichever is the greatest) to cater for studies where the amount payable under the agreement is zero or negligible. Indemnity specifically for loss of, or damage to, equipment has also been introduced;

29.10.8 The clauses on Confidentiality, Data Protection and Freedom of Information have been significantly redrafted, in large part to function as both GDPR compliant Controller/Processor Agreement and, where applicable, Data Transfer Agreement. The data transfer clauses should be deleted where Personal Data (which may include pseudonymised Personal Data – for further guidance on this point refer to the ICO Anonymisation Code of Practice) is not to be transferred from the Participating Site to the Sponsor, or any of its Agents;

29.10.9 Clause 6 (Publication) places an obligation on the Sponsor to publish the Results of the Study (replacing the previous obligation to use reasonable endeavours to publish, or otherwise disseminate);

29.10.10 Clause 7.5 allows the Participating Site to use Study Data that is also its own Clinical Data, at its own risk, for the purpose of patient care, without Sponsor permission. Clause 7.6 allows the Participating Site to use Study Data, at its own risk, for purposes other than patient care, but only with prior written permission from the Sponsor.

29.10.11 Clause 8 (Financial and Supplies Arrangements) introduces a specific obligation for invoices (in order to be valid) to be submitted in accordance with Part A of Schedule 3;

29.10.12 In Clause 10 (Termination) the clause allowing either Party to terminate the agreement without reason is replaced with a number of termination clauses and an obligation for the Participating Site to notify the Sponsor if it chooses to cease recruiting Participants (such cessation not in itself terminating the Agreement);

29.10.13 Clause 14 (Assignment and Subcontracting) removes the prohibition on sub-contracting by either Party, relying upon Schedule 2 to record any sub-contracting in place during Study set-up, placing an obligation on the Participating Site not to subsequently sub-contract without Sponsor agreement and requiring the Sponsor to notify the Participating Site if any subsequent sub-contracting on its part changes the arrangements as described in Schedule 2;

29.10.14 Clause 16 (General) provides for Sponsors to choose to allow for execution of the Agreement in counterparts;

29.10.15 Under Clause 17 (Survival of Clauses) Clauses 5 (Publicity),10.4 and 10.5 (Termination), 17 (Survival of Clauses) and Schedule 4 (Material Transfer Provisions) now additionally survive termination or expiry of the Agreement;

29.10.16 Clause 18 (Governing Law) places the Agreement under the law of the UK nation in which the Sponsor is established, unless agreed between the Parties on a claim by claim basis. Where a Sponsor is not established in the UK, the Agreement falls under the law of the UK nation in which the Participating Site is established;

29.10.17 In place of including the Protocol at Schedule 1, the Protocol is incorporated as part of the Agreement by reference in the Definitions;

29.10.18 Schedule 2 has been redrafted to clarify that, whilst responsibilities are none delegable, activities associated with those responsibilities may be delegated;

29.10.19 Schedule 4 (Material Transfer Provisions) is new and deals with the transfer of Material as defined in the Agreement. It does not remove the need for the Protocol to be clear as to the arrangements for the Material. Only when taken together with an appropriately clear Protocol does Schedule 4 comprise an adequate Material Transfer Agreement;

29.10.20 Schedule 5 (PI Declaration) has been introduced to allow Sponsors the option of obtaining a declaration from the PI(s) at the Participant Site's Site(s). Use of this schedule is optional for the Sponsor and its use does not make the PI a Party to the Agreement.