

Guidance on use of the Model Agreement for Non-Commercial Research in the Health Service (2008 Version)

PART A Context and Use of the Model Agreement

A1. Background to the development of the Model Agreement for Non-Commercial Research in the Health Service

A1.1. Sponsors of research and host institutions need to have appropriate agreements in place before a piece of research can start. With many different organisations taking on the role of Sponsor, such as universities, NHS bodies, research councils and commercial organisations, an increasing amount of resource has been used in drafting different versions of agreements for the various research scenarios. The UKCRC¹ is committed to the development of a suite of standardised model agreements for use throughout the UK. Model agreements already exist for studies that have a commercial sponsor²; this Agreement is intended to address the scenario where the Sponsor is not a commercial entity.

A1.2. The Model Agreement for Non-Commercial Research in the Health Service (mNCA) is intended to be used:

A1.2.1. To agree formally and document the relationship between, and the responsibilities of, the non-commercial Sponsor(s) (which has developed the Protocol), and the site carrying out the research (which has had no involvement in developing the Protocol). The Agreement could be used where a non-UK Sponsor has appointed a legal representative, in which case any references in the mNCA to the Sponsor refer to the Legal Representative that has been appointed in the UK. In this context, the Sponsor referred to in the mNCA takes on a Protocol developed by someone else (i.e. the non-UK Sponsor) but the Protocol is not developed by the NHS site; and

¹ The UKCRC is a partnership of organisations working to establish the UK as a world leader in clinical research by harnessing the power of the NHS. The UKCRC's aim is to re-engineer the environment in which clinical research is conducted in the UK, to benefit the public and patients by improving national health and increasing national wealth. See <http://www.ukcrc.org>

² See <http://www.ukcrc.org/activities/regulationandgovernance/modelagreements.aspx> for more information

- A1.2.2. In a range of research scenarios, including clinical trials, medical device studies, research using patient data only and research using human tissue; and
 - A1.2.3. In circumstances where the NHS Organisation recruits participants and carries out the study at the request and direction of the Sponsor (i.e. in strict adherence to the Protocol); and
 - A1.2.4. In circumstances where all of the Parties to the agreement are within the United Kingdom; and
 - A1.2.5. Without modification or negotiation of the clauses in the main body of the Agreement (the Schedules should be used to tailor the Agreement to specific research situations).
- A1.3. This mNCA has been developed jointly by the 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. Three rounds of consultation have been undertaken on the proposed approach. Extensive comments were received at each stage which have been reviewed in detail and used to develop the mNCA. Support has been strong throughout for the development of a short model agreement comprising a set of compulsory terms and variable schedules.
- A1.4. Mills and Reeve LLP have provided legal advice on the content of the Agreement and the accompanying guidance.
- A1.5. We propose that the Agreement will be reviewed and revised approximately 12 months after publication to take into account user experience and changes in the research infrastructure.

A2. Parties to the Agreement

- A2.1. All research projects involving either participants recruited by virtue of their being NHS³ patients or data accessed through the NHS and carried out by NHS/HSC bodies should be governed by contracts between the Sponsor and the NHS

³ In the context of this guidance and the agreement "NHS" refers to the National Health Service (in England, Scotland and Wales) and Health and Social Care (HSC) in Northern Ireland. In April 2007 HSC replaced the previous title of Health and Personal Social Services (HPSS) in Northern Ireland.

Organisation⁴ responsible for carrying out the research. This ensures compliance with research governance requirements and establishes the correct lines of accountability for those involved in research projects. In no circumstances should an individual from either the Sponsor or the NHS Organisation enter into a contract themselves.

- A2.2. In the mNCA, the Sponsor is the body that has taken responsibility for the development of the Protocol. The Sponsor could be a number of different types of public sector or charitable bodies such as another NHS body, a university, a government department, research council or a research funder. The Sponsor may be more than one organisation and the mNCA makes provision for there to be more than one Sponsor.
- A2.3. Where there is more than one Sponsor⁵ their respective roles need to be clearly stated in Schedule 2. The 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 given by one Sponsor is deemed to have been given on behalf of all of them. Should Sponsors wish to vary any such provision, it should be done by way of a separate agreement between the Sponsors.
- A2.4. The “NHS Organisation” as the contracting body will always be the NHS body responsible for carrying out the research. This may be any form of NHS body in England, Northern Ireland, Scotland and Wales.⁶ The Agreement envisages that the NHS Organisation has not been involved in developing the Protocol.

⁴ In this context, NHS Organisations include Health and Social Care (HSC) organisations established in Northern Ireland

⁵ Under Regulation 3 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (<http://www.uk-legislation.hmso.gov.uk/si/si2004/20041031.htm>) the role of Sponsor can be undertaken by:

- A single individual or institution
- A group of individuals or institutions that divide the responsibilities and liabilities; this is termed “Co-Sponsorship”
- A group of individuals or institutions that share the responsibilities jointly; this is termed “Joint Sponsorship”. Joint Sponsors are jointly liable for all the duties of Sponsor

⁶ Where for example a Primary Care Trust wishes to engage one or more GP or other primary care contractor to carry out the research and such GP, dentist or other primary care contractor is not an employee of the Primary Care Trust but provides health services under a GMS, PMS or similar primary care contract, then it is not appropriate to use the mNCA.

- A2.5. The ultimate source of funding could be from a commercial entity but that entity is not a party to the mNCA.
- A2.6. The key element that makes this Agreement non-commercial is that the Sponsor of the research study is not a commercial entity.

A3. Use of the Agreement

- A3.1. Use of the mNCA is voluntary. However, as it has been structured to meet the requirements of non-commercial Sponsors and the NHS bodies undertaking the research, it reflects an appropriate risk sharing between Sponsor and NHS Organisation. It is therefore recommended by its stakeholders and those who have endorsed its use.
- A3.2. Use of the mNCA is intended without modification or negotiation of the clauses in the main body of the Agreement. Only the Schedules will need tailoring to the specific research situations.
- A3.3. It is designed for use in a number of different scenarios including:
 - A3.3.1. Between any public sector or charitable organisation and an NHS body where the public sector or charitable organisation is the Sponsor and the NHS body is carrying out the research; or
 - A3.3.2. Between NHS bodies where one or more NHS body is the Sponsor and research will be carried out in another NHS body; or
 - A3.3.3. Where there is one or more Sponsor from different public sector/charitable bodies, including NHS bodies, and research is carried out in an NHS body; or
 - A3.3.4. For multi-site trials where it is envisaged that it would form one of a number of contracts entered into by the Sponsor as the Sponsor would need an agreement in place with each site.
 - A3.3.5. In any of the above situations where the research is carried out by an investigator whose substantive contract of employment is with a university

and the investigator has an honorary research contract with the NHS Organisation⁷.

A3.4. The mNCA is not designed for use:

- A3.4.1. In collaborative research projects where the various bodies co-fund the research and/or jointly develop the Protocol; or
 - A3.4.2. In commercial research sponsored by pharmaceutical companies or any other commercial corporate entity; or
 - A3.4.3. Where the funder is a commercial entity and such funder wishes to be a party to a contract with the NHS Organisation; or
 - A3.4.4. Any research involving patients or their tissue or data which is not carried out by a NHS Organisation in or through the NHS; or
 - A3.4.5. Where the research is carried out by an entity other than by the contracting NHS body – e.g. if an independent General Practitioner (GP) proposes undertaking the research on behalf of a Primary Care Body; or
 - A3.4.6. For use by an individual employee within a Sponsor or an NHS body to carry out research in a personal capacity.
- A3.5. 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, and agreements between Sponsor and other sites, including additional copies of the mNCA

A4. What types of research are covered by the mNCA?

- A4.1. The mNCA has been developed for use in a range of research scenarios. These include clinical trials, medical device studies, research using patient data only and research using human tissue.

⁷ See the Research Passport system for issuing honorary research contracts to researchers with no contractual arrangements with the NHS, and who carry out research in the NHS that affects patient care (<http://www.ukcrc.org/activities/regulationandgovernance/researchpassport.aspx>).

A4.2. The terms and conditions are suitable for all such scenarios. Only completion of the Schedules will differ depending on the type of study involved (see Part C below).

A5. Devolved administrations

A5.1. Unlike the commercial versions of model agreements, the mNCA has been developed as a single UK-wide agreement. This means that it can be used when the NHS Organisation carrying out the research and/or the Sponsor are in England, Northern Ireland, Scotland and/or Wales. The mNCA takes into account jurisdictional differences in its wording.

A6. The involvement in research projects of an Investigator whose substantive contract of employment is with a university

A6.1. In some projects one or more investigators will be employees of a university rather than employees of the NHS Organisation carrying out the research. In these circumstances it is essential that:

A6.1.1. Where appropriate⁸, an honorary research contract is in place between the university employee and the NHS Organisation

A6.1.2. There is clear understanding between all the parties about responsibilities and liabilities (see paragraph B 2.2 below).

A6.2. It will also be important for the NHS Organisation to review the terms of the honorary research contract before entering into the mNCA to ensure there is consistency between the two documents. Particular clauses that will need checking are those dealing with confidentiality and intellectual property rights. If these are inconsistent or the honorary contract does not address them then further agreements may need entering into between the university and NHS Organisation. Refer to the Appendix of this guidance for a model assignment of Intellectual Property Rights.

A6.3. The NHS Organisation must ensure that the university is aware of the involvement of the investigator in the project well in advance of the research commencing, and ideally of the mNCA being signed.

⁸ Refer to the Research Passport Resource pack at:
http://www.nihr.ac.uk/systems_research_passports.aspx

A7. How to complete the Agreement and what should not be amended and why

A7.1. The mNCA has been developed to ensure that only project-specific amendments are necessary. The terms and conditions have been drafted to cover the essential legal provisions in relation to all types of research projects and these should not be amended. The following elements will need completing:

A7.1.1. Front page insert:

A7.1.1.1. Date.

A7.1.1.2. Name and address of NHS Organisation carrying out research.

A7.1.1.3. Name and address of all Sponsors.

A7.1.1.4. Full title of research study.

A7.1.2. Each page insert:

A7.1.2.1. Short title of research study.

A7.1.2.2. Reference number.

A7.1.3. Sign Off section on page 12:

A7.1.3.1. The signature of authorised representative of the NHS Organisation.

A7.1.3.2. The signature of the authorised representative of the Sponsor or of each Sponsor if more than one.

A7.1.3.3. Each person must add their name, position and date of signature.

A7.1.4. Schedules (see Part C for details)

PART B Terms and Conditions

A core objective in the development of the mNCA was to produce a concise agreement. This objective has been applauded in consultations. Given the brevity of the agreement it is essential not to change the terms and conditions.

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. The thorny legal area of liability is however expanded in more detail.

B1. Legal and regulatory framework

- B1.1. 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.
- B1.2. The mNCA avoids listing all applicable legislation for two reasons. Firstly not all legislation will apply to each study. Secondly legislation in this area is introduced and updated frequently.
- B1.3. Clause 2.1 of the Agreement therefore takes a broad brush approach of ensuring that all parties will comply with all relevant laws, regulations and codes of practice applicable to the *individual* agreement being signed. It will be for those involved in each study to ensure they are aware of all current law applicable to their study.
- B1.4. The core pieces of legislation that may apply to particular types of research are:
 - B1.4.1. Medicines for Human Use (Clinical Trials) Regulations 2004. These regulate trials of medicines on people.
 - B1.4.2. Medical Devices Regulations 2002. These regulate the placing on the market and use of medical devices. These Regulations were amended in 2003.
 - B1.4.3. Human Tissue Act 2004 / Human Tissue (Scotland) Act 2006. This regulates the collection, storage and use of human tissue.
 - B1.4.4. The Blood Safety and Quality Regulations 2005 and subsequent amendments regulate blood establishments and hospital blood banks.
 - B1.4.5. The Human Fertilisation and Embryology Act 1990 which regulates the creation, storage and use of embryos.
- B1.5. More advice as to the relevant legislation can be found on the following organisation's websites:-
 - B1.5.1. The Medicines and Healthcare products Regulatory Agency, see <http://www.mhra.gov.uk>

- B1.5.2. The Human Tissue Authority, see <http://www.hta.gov.uk/>
- B1.5.3. The Human Fertilisation and Embryology Authority, see <http://www.hfea.gov.uk/>
- B1.6. 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 research such as if hazardous material or genetically modified organisms are used. Patient consent and confidentiality is closely regulated in particular by the Data Protection Act 1998 and by Codes of Practice and this is discussed at paragraph 3 below. The Mental Capacity Act 2005 and Adults with Incapacity (Scotland) Act 2000 specifically addresses issues of capacity to consent to involvement in research.
- B1.7. Clause 2.1.1 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. There are various versions and the one that should apply to those carrying out research is the latest one to be incorporated into UK legislation (See the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended).
- B1.8. 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 they comply with any such guidance or terms of reference. As compliance with the relevant research framework is key to carry out research in the NHS, it is a specific contractual obligation that all Parties to the mNCA comply with the applicable research framework be it the Research Governance Framework for Health and Social Care (second edition) issued by the Department of Health for England, or the Research Governance Framework for Health and Social Care in Northern Ireland or the Scottish Executive Health Department Research Governance Framework for Health and Community Care (second edition) for Scotland or the Research Governance Framework for Health and Social Care in Wales (2001)⁹.

⁹ The current Research Governance Frameworks can be accessed through the Health Department websites:

- The Research Governance Framework for Health and Social Care (second edition) issued by the Department of Health for England (2005) see: http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/DH_4002112

B1.9. Depending on the nature of the research, approval must be sought from one or more body before the research can commence. Responsibility to apply for such approval is detailed in Schedule 2 and at clause 3.1.2 there is an obligation on all Parties to conduct the research in accordance with the relevant approvals.

B2. Liability

B2.1. 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 4 apportions responsibility between Sponsor and NHS Organisation.

B2.2. Negligence

B2.2.1. Liability for clinical negligence on the part of NHS Organisation staff conducting research, including an investigator engaged under an honorary research contract, lies with the NHS Organisation. A NHS Organisation in England, Wales or Northern Ireland will be indemnified for such clinical negligence by the appropriate risk sharing scheme (be it the Clinical Negligence Scheme for Trusts in England, Welsh Risk Pool or Clinical Negligence Central Fund in Northern Ireland) provided those involved in the research project obtain management permission from their organisation before conducting any research. In Scotland, permission will similarly be necessary from the relevant Health Board.

B2.3. Non-Negligent Harm.

B2.3.1. The 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.

B2.3.2. NHS Organisations and some other public bodies cannot offer to compensate participants in these circumstances in advance of any harm occurring. Nor

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- The Research Governance Framework for Health and Social Care in Northern Ireland (2006) see http://www.centuralservicesagency.n-i.nhs.uk/files/rdo_whats_new/file/RGF_061106.pdf
 - The Scottish Executive Health Department Research Governance Framework for Health and Community Care (second edition) for Scotland (2006) see www.cso.scot.nhs.uk/publications/ResGov/Framework/RGFEdTwo.pdf
 - The Research Governance Framework for Health and Social Care in Wales (2001) see: <http://new.wales.gov.uk/topics/health/word/publications/governance/?lang=en>

can they take out commercial insurance for non-negligent harm. Any such payment, called an *ex gratia* payment, can only be considered at the time the harm occurs.

- B2.3.3. Research Ethics Committees must consider if 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, then the research will only receive a favourable opinion if a Sponsor that is able to do so is willing to provide insurance for non-negligent harm.

B2.4. Other Forms of Loss and Damage.

- B2.4.1. Liability can arise in a variety of other ways. For example:

B2.4.1.1. 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

B2.4.1.2. 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

B2.4.1.3. The research project may use third party confidential information which is breached and the third party seeks to recover any loss they suffer.

B2.5. Clause 4 provisions

- B2.5.1. 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:

B2.5.1.1. Clause 4.1 states the general legal position regarding death and personal injury arising from negligence.

B2.5.1.2. Clause 4.2 – The Sponsor indemnifies the NHS Organisation where liability arises from the NHS Organisation undertaking the research in accordance with the Protocol or from assembling, manufacturing, or preparing medicines or equipment on the Sponsor's specific instructions. The reasoning behind this is that the Protocol is a document prepared by the Sponsor usually well in advance of the NHS

Organisation being asked to carry out the research. As the NHS Organisation is expected to comply with it, then any liability that arises from the NHS Organisation doing so should be a Sponsor responsibility and not one that is passed onto the NHS Organisation. However, the scope of the indemnity is limited. The NHS Organisation 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 or if the loss arose from negligence or breach of statutory duty of the NHS Organisation. The indemnity does not apply if the Sponsor is an NHS body, as NHS bodies cannot as a general rule indemnify one another (see Clause 4.6).

B2.5.1.3. Clauses 4.5 to 4.8 address respective liability where both Sponsor and NHS Organisation are NHS bodies.

B2.5.1.4. Clause 4.6 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.

B2.5.1.5. Clause 4.7 addresses circumstances where the parties are NHS bodies in Scotland as different rules apply, where the parties are NHS bodies in different jurisdictions and where the loss is not covered by one of the risk sharing schemes, and the NHS bodies self insure. 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 as laid down in relevant legislation.

B2.5.2. The consensus approach to the Agreement is that it is inappropriate to include caps on liability. The Agreement will be between public sector and/or charitable bodies and each party should take responsibility for its own acts or omissions rather than seeking to transfer risk and responsibility as one may do with a commercial entity. There is, however, one specific area of liability where the Agreement does include a cap on liability.

B2.5.3. Should an NHS Organisation be in breach of its obligations under the Agreement, then, where a third party funds the Study in some manner, the Sponsor could in turn be in breach of its obligations to such third party. The NHS Organisation is not a party to such agreement between Sponsor and third party, it has no control over its provisions, yet the NHS Organisation is potentially exposed should there be no limits of liability within the Sponsor/third party agreement. If the funder seeks to recover its loss from the Sponsor the Sponsor may in turn seek to recover these losses from the NHS Organisation. As the extent of liability the Sponsor is prepared to assume in relation to the third party is something within the control of the Sponsor and not the NHS Organisation, it was seen as appropriate to limit the liability of the NHS Organisation “in respect of any contractual liability the Sponsor may or does incur to a third party”. This does **not** limit liability of the NHS Organisation for third party death or personal injury, only for contractual liability. This principle is reflected in clause 4.9.

B3. Confidentiality

- B3.1. All parties will be bound by legal obligations of confidentiality in respect of patient information. The form of consent obtained from Participants should therefore be consistent with the Protocol and proposed use of patient information.
- B3.2. Under the mNCA the NHS Organisation must treat the Results as confidential. The reason for this is to protect the Sponsor should a funder have required such a provision in its arrangements with the Sponsor. It will, therefore, be important for the NHS Organisation to obtain the written consent of the Sponsor before using the results in any form of publication or disclosing the Results of the research in any other way.

B4. Publicity

- B4.1. Clause 6.1 of the Agreement requires the consent of the other Party to the Agreement to use their name, logo or a registered image in any publicity, press release or advertising and for the timing and content of publicity and advertising to be agreed between the Parties. This provision is wide enough to catch virtually all forms of communication including organisation wide internal announcements that the project is proceeding.

B5. Publication

B5.1. The various Research Governance Frameworks state that there should be free public access to the findings of research, thus placing NHS Organisations under a responsibility to publish the results of research projects. At the same time, Sponsors may need to protect proprietary information prior to publication or may be conducting a multi-site trial and wish to publish the results of the full trial before subsets of the data are published. In balancing these potentially differing interests and obligations, clause 7 provides for first publication by the Sponsor but imposes an obligation on the Sponsor to do so. Subsequent publication by the NHS Organisation is subject to the written consent of the Sponsor, and the Sponsor must behave reasonably in deciding on this. It is particularly important for the NHS Organisation to obtain consent given that the NHS Organisation must treat the Results as confidential information. In considering whether or not to give consent the Sponsor must have regard to the obligations on NHS Organisations to publish their work.

B6. Intellectual Property

B6.1. 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.

B7. Interpretation of terms “intellectual property” and “know-how”

B7.1. Although for the sake of simplicity and brevity the terms “intellectual property” and “know-how” have not been defined in the agreement, they are intended to encompass all forms of intellectual property and know-how. Stakeholders involved in developing the mNCA have developed these clauses on the basis that intellectual property and know-how is given the same meaning as in the model Clinical Trials Agreement. Therefore,

B7.1.1. Intellectual property covers: “patents, trade marks, trade names, service marks, domain names, copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including application for registration of any of them”.

B7.1.2. Know-how covers: “all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protected as intellectual property or any application for registration as such”.

B8. Ownership

B8.1. The principles in the mNCA around ownership of intellectual property and know-how are as follows.

B8.1.1. Each Party retains ownership of any intellectual property or know-how they owned prior to the start of the Study.

B8.1.2. All intellectual property and know-how in the Protocol, Results or otherwise arising directly from the Study is owned by the Sponsor or 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 NHS Organisation carrying out the Study. The mNCA is not for use where the Parties are carrying out collaborative research. 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, they need to consider dealing with intellectual property issues separately. At such time it is relevant to consider the extent of this contribution, who should own the intellectual property rights in it, how the NHS Organisation 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 NHS Organisation should share in the reward of this.

B8.2. However, it is envisaged that these circumstances arising will be by exception and that the role of the NHS Organisation 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 NHS Organisation.

B8.3. Ownership of Intellectual Property Rights by the Sponsor is, nonetheless, narrowly drawn. Should the NHS Organisation develop (a) any improvements to the Protocol, Results or the Study generally, (b) clinical procedures or (c) intellectual property rights indirectly associated with the Study (for example, exploring use of the same drug to treat a wholly different disease from that under study), then such intellectual property rights in these activities do not pass to the Sponsor. This does not of itself mean the NHS Organisation can use such intellectual property rights as that will depend on the extent they themselves are derived from the Sponsor's intellectual property but it provides for the NHS Organisation to own rights that are outside the direct scope of the Study.

B9. Obligations of the NHS Organisation

B9.1. As all intellectual property rights and know-how in the Protocol and in the Results and arising directly from the Study belong to the Sponsor, to give effect to this clause the NHS Organisation must ensure that it owns all intellectual property rights of those carrying out the research. This means that where individuals who are not employed by the NHS Organisation are involved in the Study, these individuals or their employer (where they are employed by a third party), must assign any intellectual property rights that they may generate to the NHS Organisation before that individual starts work on the Study. A model assignment is attached as an Appendix to this Guidance (at page 22).

B9.2. The Sponsor owns the property in any material that derives from biological material provided to the Sponsor. The NHS Organisation must ensure it obtains informed consent from all patients for potential use of any such samples and an acknowledgement that patients have no property rights in any donated material or its derivations. The Sponsor and NHS Organisation should enter into a Materials Transfer Agreement before the material is transferred. A Materials Transfer Agreement is appropriate for use in the transfer of materials such as cell lines, chemicals, proteins, bacteria. Such agreement should clearly define the materials being transferred, the way in which the Sponsor can use the materials, the extent to which the materials should be protected as confidential, disposal of unused materials and ownership of intellectual property rights in the material and any modifications of or inventions that derive from the materials. It will be important to ensure that the terms of a MTA are consistent with the mNCA, particularly regarding ownership of materials and confidentiality.

B10. Use of Intellectual Property Rights

- B10.1. One Party may use another Party's pre-existing intellectual property rights in carrying out the research.
- B10.2. There is no ongoing right of the NHS Organisation to use the intellectual property rights in the Protocol, Results or otherwise directly arising from the Study. The NHS Organisation can use know-how gained during the Study in its usual activities but care needs to be taken in doing so that this does not involve use of the Results. These are confidential and the NHS Organisation cannot use the Results without the Sponsor's permission.

B11. Governing law

- B11.1. As the mNCA is intended for UK-wide use, the governing law and court with jurisdiction over the Agreement (clause 19) is that of the country where the Site is based. This can be overridden at the election of the Parties and any such change must be in writing. This should be considered by the Parties before signing the Agreement.

PART C Schedules

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

C1. Schedule 1 – Protocol

- C1.1. The Protocol is a core document in a research study setting out the objectives, design, method, statistical and organisational arrangements of the Study. It should be attached to Schedule 1. In most circumstances the provision of the Protocol will take precedence over the provisions of the mNCA. However, there are four areas where the consensus was that the terms of the mNCA should prevail. These are:
- C1.1.1. Liabilities and indemnities
 - C1.1.2. Confidentiality, data protection and freedom of information
 - C1.1.3. Publication
 - C1.1.4. Intellectual property rights.
- C1.2. It will be important therefore for all parties to ensure that there are no contradictory provisions between the Protocol and the mNCA, particularly in the four areas

mentioned above and if any exist these should be resolved before signing the mNCA. This is important as the application form for ethical approval and the form a favourable opinion takes are based on adherence to the Protocol. Any inconsistencies may result in amendments to the Protocol and require further approvals.

- C1.3. Schedule 1 provides for key information to be inserted regarding details of organisations and individuals involved in the project, numbers of participants and samples required for the Study and the dates of the main milestones of the Study.

C2. Schedule 2 – Division of Responsibilities

- C2.1. The aim of this Schedule is to remind those involved in a research project of their key responsibilities and who usually assumes respective responsibilities. It is not intended to be an exhaustive list and will vary from project to project.
- C2.2. Parties should set out the agreed division and/or delegation of responsibilities in the table contained in the Schedule. Those responsibilities grouped in the first eight boxes 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.
- C2.3. Where there is more than one Sponsor, the name of the Sponsor responsible for each activity should be given.
- C2.4. Where both the Sponsor and NHS Organisation are named in respect of a particular responsibility, liability for such responsibility is not joint and several. 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.
- C2.5. It is intended that all capitalised terms used in this Schedule but not otherwise defined in the Agreement should be interpreted in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004

C3. Schedule 3

- C3.1. This Schedule covers a number of important elements as follows:
- C3.2. It provides for the financial arrangements for the research project – 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.
- C3.3. The costs paid by the Sponsor and contained in the Schedule may typically include, but are not limited to, the costs of:
- C3.3.1. Screening;
 - C3.3.2. Visits;
 - C3.3.3. Provision of pharmaceuticals; and
 - C3.3.4. Use of diagnostic tools.
- C3.4. When setting up the Study it will be important for the NHS Organisation to consider all financial issues and ensure recovery of full NHS costs associated with carrying out the research¹⁰. These may also include:
- C3.4.1. Staff costs including administrative staff and costs of staff employed under a honorary research contract.
 - C3.4.2. Services costs such as clinics, bed days, imaging, pharmacy costs.
 - C3.4.3. Administrative costs and other overheads.
 - C3.4.4. Travel and related expenses.
- C3.5. The Schedule addresses the possibility of items being provided to the NHS Organisation by the Sponsor or a third party or obtained by the NHS Organisation 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,

¹⁰ NHS Organisations should cost in accordance with appropriate guidance, such as the NHS Finance Manual. Costs included should be those classified as research costs and not those covered by service support or treatment costs

insurance and storage arrangements, training and maintenance of the items and what happens to them at the end of the Study.

- C3.6. Finally the name and address of each Party for the delivery of formal notices must be included in this Schedule.

December 2008.

APPENDIX

MODEL ASSIGNMENT OF INTELLECTUAL PROPERTY RIGHTS

THIS ASSIGNMENT OF INTELLECTUAL PROPERTY RIGHTS is made on [INSERT DATE]

BETWEEN:

- (1) [INSERT NAME OF PERSON/ORGANISATION CARRYING OUT RESEARCH] [INSERT ADDRESS] (“Assignor”);
- (2) [INSERT NAME OF NHS ORGANISATION] [INSERT ADDRESS] (“Assignee”).

WHEREAS:

- (A) The Assignee has entered into an agreement with a third party to carry out research for a study titled [INSERT NAME OF STUDY]
- (B) The Assignor has agreed to take part in the research and agreed that all intellectual property rights in and to any work created or invented by the Assignor as part of the research project shall belong to the Assignor on the terms set out below.

IT IS AGREED:

1. Definitions

“**Intellectual Property**” patents, trade marks, trade names, service marks, domain names, copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including application for registration of any of them.

“**Intellectual Property Rights**” means all Intellectual Property arising from or relating to the Project.

“**Project**” means the research being carried out by the Assignee as part of the clinical research study.

2. Assignment

2.1 In consideration of payment of the sum of £1 (receipt of which the Assignor hereby acknowledges), the Assignor assigns to the Assignee with full title guarantee by way of present and future assignment all Intellectual Property Rights.

3. Warranties

3.1. The Assignor warrants now and as a continuing warranty that the Intellectual Property Rights are and will be its original work, and have not been and will not be copied wholly or substantially from any other source, and that the use or further assignment by the Assignee of the Intellectual Property Rights assigned to it hereunder will not infringe the rights of any third party.

4. Further assurance

4.1. The Assignor shall do or procure to be done all such further acts and things, and execute or procure the execution of all such other documents, as the Assignee may from time to time reasonably require in order to give the Assignee the full benefit of this Agreement, whether in connection with any registration of title or other similar right or otherwise.

5. Waiver of moral rights

5.1. The Assignor waives absolutely its moral rights arising under Chapter 4 of the Copyright, Designs and Patents Act 1988 and, so far as is legally possible, any broadly equivalent rights he may have in any territory of the world.

6. Governing law and jurisdiction

6.1. This Agreement shall be governed by and construed in accordance with the law of [England and Wales] [Scotland] [Northern Ireland] and the parties submit to the exclusive jurisdiction of the courts of [England and Wales] [Scotland] [Northern Ireland] over any claim or matter arising under or in connection with this Agreement.

This Agreement has been entered into on the date stated at the beginning of it.

Signed by [INSERT NAME AUTHORISED
SIGNATORY]

for and on behalf of [INSERT NAME OF
ASSIGNOR]

Signed by [INSERT NAME OF
AUTHORISED SIGNATORY]

for and on behalf of [INSERT NAME OF
ASSIGNEE]