



Guidance on use of the 2008 model Clinical Investigation Agreement for medical technology industry sponsored research in NHS hospitals

INTRODUCTION

Background to the development of the model Clinical Investigation Agreement

The model Clinical Investigation Agreement (mCIA) for company-sponsored commercial research involving medical devices was developed under the auspices of the Healthcare Industries Task Force (HITF) and in collaboration between the DH and the Association of the British Healthcare Industry (ABHI). Negotiations between representatives of the various stakeholder interests (Health Departments from England and the Devolved Administrations, the MHRA, the ABHI, NHS hospitals and companies in the medical device industry), were undertaken with the objective of devising a model agreement that would be accepted, without modification, by all medical technology companies and all NHS hospitals throughout the UK. It was intended that the resulting model CIA would be widely adopted and carry an authority equivalent to that of the ABHI Form of Indemnity, without its use being legally mandatory.

The development of a model agreement for medical device studies is the next step in the creation of a suite of templates for commercial research contracts for use throughout the NHS. The development of model agreements for commercial contract clinical research carried out in NHS hospitals was first recommended by the Pharmaceutical Industry Competitiveness Task Force (PICTF) as one of the ways to increase the speed and efficiency of clinical trial management and contribute to making the UK a more attractive site for international multi centre trials. The implementation of this initiative resulted in the publication of: the first Department of Health (DH)/Association of British Pharmaceutical Industry (ABPI) model Clinical Trial Agreement (mCTA) for pharmaceutical research in 2003; the revised version published by DH, the ABPI and the BioIndustry Association (BIA) in 2006 and (in association with the Clinical Contract Research Association, CCRA) the CRO mCTA for trials managed by Contract Research Organisations in 2007. These agreements have now been adopted by virtually all pharmaceutical and biopharmaceutical companies operating in the UK, and by NHS hospitals, as their core templates for their commercial contract clinical trial agreements. Versions have been published with the terms modified to

reflect the different organisational arrangements and, where necessary, legal systems of Scotland, Wales and Northern Ireland. Although the use of the relevant versions of the model agreements is not legally mandatory anywhere in the UK, their use removes the need for company-by-company, investigation-by-investigation and site-by-site legal review of contract terms.

In the case of pharmaceutical and biopharmaceutical trials, where model agreements have now been in place for a considerable time, their use has been found to achieve the aims of reducing the time for companies' and hospitals' R&D administrations to approve and sign off arrangements for the initiation of trials. Combined with the fact that both the MHRA and the National Research Ethics System now reliably achieve their administrative timelines, conditions are in place for overall improvements in the speed and efficiency of the approval of pharmaceutical clinical trials and of clinical trial management in the NHS. After publication of the mCIA, it is intended that similar improvements will be demonstrable in the speed and efficiency of approval of both regulated and post market medical technology clinical investigations. Early indications from ABHI members who have used draft versions of the mCIA for their studies appear to confirm these expectations. A review of experience with the mCIA will be carried out after one year, overseen by the Ministerial Medical Technology Strategy Group.

Categories of studies

Not all clinical studies supported by the medical technology industry are "Contract Clinical Investigations". It is important to distinguish "Contract Clinical Investigations" from "Collaborative Clinical Research", including investigator-led commercial investigations. In the context of this agreement, "Contract Clinical Investigations" are defined as commercial, industry-sponsored investigations of investigational or marketed medical devices, involving NHS patients, undertaken in NHS hospitals. Clinical Investigations classified as "Collaborative Clinical Research" (investigator-initiated commercial clinical research in which a large proportion of the funding is provided by a commercial partner), which can include pre-market and post-market studies and may involve current NHS patients, will continue to be covered by contracts between the company providing resources for the study (which may for example include funding or the provision of medical device supplies) and the holder of the investigator's substantive employment contract, whether that be a university or NHS body. See next section, and discussion of clause 10 in part 2 of this Guidance. The mCIA is not intended for use in performance evaluations of IVDs.

Adoption of the 2008 mCIA

The terms of the 2008 mCIA, negotiated by the Departments of Health for England and the Devolved Administrations, the ABHI, NHS hospitals and medical technology companies have been endorsed by the Ministerial Medical Technology Strategy Group; the NHS Confederation; NRES; MHRA; the Medical Schools Council; the NHS R&D Forum; the UK Clinical Research Collaboration (UKCRC). The publication of the mCIA has been considered by the Foundation Trust Network. The Network recognised that the mCIA had been negotiated by a group which included some FTs with extensive experience of, and involvement in, clinical trials. FT Network members take the view that it is very helpful to have a model contract with which to work. The agreement, negotiated with English law and governance arrangements at its core, has been appropriately modified for use under the legal systems and administrative arrangements of Wales, Northern Ireland and Scotland. The organisations that have developed and endorsed the mCIA commend its use without modification.

Investigations involving medical academics and other University-employed staff

The Department of Health in England published the Research Governance Framework in 2005¹, which clarified contracting arrangements for commercial clinical investigations. This requires that, for governance reasons, commercial investigations classified as “Contract Clinical Investigations”, must in all cases take place under an agreement between the commercial sponsor and the NHS body responsible for the investigation site (RGF v2, paragraph 3.2.4). This contracting arrangement is required whether the investigator is substantively employed by the NHS body or by an associated academic body. In the case of investigations in which the investigator or other investigation site team member is an employee of a University, the NHS body undertaking the investigation (with whom the researcher will have an Honorary Contract), must notify the University employer about the proposed research and discuss the costs arising from it. In due course, appropriate transfers of income arising from the medical academic’s work, and that of any other University-employed staff, will take place. The model CIA contains provisions that require such notifications to be made and discussions about costs and reimbursements to take place. The basis for reimbursement of universities should be made explicit in the investigation contract by inclusion in the financial schedule.

Industry-sponsored healthy volunteer studies

The model CIA is not for use for such investigations and this guidance does not apply to them. If such studies are carried out by investigators whose substantive employment contracts are with universities, the contracts should be between the sponsor and the university.

Structure of the Guidance

This guidance has been developed to facilitate the use of the model CIA. Use of the mCIA is not mandatory for either NHS hospitals or member companies of either the ABHI or other medical technology trade associations. However, its routine use is strongly commended by the UK Departments of Health in England and the devolved administrations of Wales, Northern Ireland and Scotland; and the ABHI. These bodies recommend that no modifications are made to the agreement, other than those necessary to correctly identify the investigation, the contracting parties, and the investigator, and set out the financial terms and clinical investigation subject recruitment arrangements.

This guidance is in 3 parts:

Part 1 summarises recommendations made by the Healthcare Industries Task Force (HITF), the establishment of the UK Clinical Research Collaboration, and findings from a report for the UKCRC Industry Road Map Group concerning the industry’s view of the UK environment for carrying out clinical studies of medical devices and the UK’s international competitiveness and the national and international regulatory framework for clinical investigations of medical devices.

Part 2 contains a commentary, drafted collaboratively by the NHS, DH and its industry partners explaining the importance and implications of a number of the key terms of the model CIA. These include an extensive discussion of registration of investigations and the publication of headline results arising from them. It also contains guidance on the issues that need to be negotiated in the process of developing a CIA specific to the

¹ http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/DH_4002112

clinical investigation under discussion. It explains the discussions that should take place with universities employing medical academics who take on the role of investigator in Contract Clinical Investigations.

Part 3 identifies a recommended sequence of steps in the process of negotiating terms for NHS hospitals' corporate approval of industry-sponsored clinical investigations, and contact points for enquiries about the model CIA.

Terminology

In this guidance, the research site is referred to as 'NHS hospital' or 'NHS body', which are generic terms for the corporate bodies that undertake clinical investigations. In England and Wales, this will have the meaning of NHS Trusts and NHS Foundation Trusts; in Northern Ireland, it means Health and Social Care (HSC) hospitals and HSC Trusts; and in Scotland, it means Health Boards. The national versions of the model CIA include text options for the different corporate terms.

PART 1

Background to the formulation of guidance on Clinical Investigation Agreements (CIAs)

1. Healthcare Industries Task Force (HITF)

- 1.1 The Healthcare Industries Task Force (HITF) was established to explore issues of common interest and identify opportunities for co-operation that would bring benefits for patients and service users, health and social care services, and the healthcare technology industry. It was a joint, year-long initiative which addressed a number of issues of common interest and agreed a range of solutions to problems, or improvements that would bring benefits for patients, the NHS, the national economy and industry.
- 1.2 The areas of focus were market access, R&D and the industrial base, regulatory issues and international trade. The central themes which emerged were how to stimulate innovation in the NHS and industry and how to increase adoption of new useful medical technologies. HITF recognised the importance of the UK Clinical Research Collaboration (UKCRC), which was established during the HITF initiative, and was keen to ensure that the healthcare industries fully engaged with it to ensure that there was a better understanding of the conditions needed for clinical investigations with medical devices, and that opportunities for the clinical development of innovative products and procedures were maximised. Industry is represented at all levels of the UKCRC.
- 1.3 In response to the threat of the UK losing its leading position in commercial clinical research, the UKCRC initiated a project which suggested initiatives to strengthen the value proposition to industry. Manufacturers across the pharmaceutical, biotech and healthcare technology sectors were interviewed and surveyed for their views of the UK as contributors to a UKCRC commissioned review carried out in August 2005, "Clinical Research in the UK: Towards a single system that reliably delivers a distinctive quality and rapid access at reasonable cost" Findings across industry segments showed that the five major criteria for choosing where to locate clinical research were strategic relevance, quality, time, reliability and cost. Stakeholders suggested that removal of the bureaucracy and barriers that made trial set-up complicated and cumbersome could significantly increase the amount of commercial clinical research performed in the UK.

2. Improved Research Governance of studies carried out in the NHS

- 2.1 A number of changes have taken place in recent years aimed at ensuring that clinical research is of the highest achievable scientific and ethical standard. Several of these changes have been introduced at the international level, including the good clinical practice guidance in International Standard EN ISO 14155, parts 1 and 2, (Clinical Investigation of Medical Devices for Human Subjects) and the International Committee on Harmonisation Good Clinical Practice Guideline (ICH GCP).
- 2.2 In the UK, the introduction of the Research Governance Framework for Health and Social Care set in place a comprehensive set of principles for the organisation, management and corporate governance of research within healthcare. In April 2005 a revised version was published in England and revisions are planned or have been published by the devolved administrations elsewhere in the UK.
- 2.3 The importance of appropriate lines of accountability for all researchers undertaking studies involving NHS patients and clinical samples obtained from them was emphasised in the Follett Report 'A Review of Appraisal, Disciplinary and Reporting

Arrangements for Senior NHS and University Staff with Academic and Clinical Duties'². That Report's conclusions on reporting arrangements for academic staff with clinical responsibilities are of particular importance. They underlie the recognition that the contractual arrangements for clinical investigations sponsored by industry most appropriately lie in the domain of the Chief Executive of the NHS body responsible for the clinical care of the patients involved in the study.

3. Panel of NHS Research Ethics Committees for medical devices applications

In 2006, the National Research Ethics Service established a panel of ethics committees with experience of assessing medical technology research protocols. The Medicines and Healthcare products Regulatory Agency (MHRA) and ABHI representatives delivered several training programmes on medical devices and clinical research to ethics committee members. Detailed guidance on ethics approval of medical devices clinical research and communication with the regulator MHRA was published in April 2008.

4. Clinical investigations in the NHS

To remedy observed problems with investigation initiation, ethics review, recruitment, data quality and cost, a programme to improve clinical investigation performance at sites in the UK has been initiated, focusing on three areas of governance and site management:

- Ensuring that contractual arrangements made between companies sponsoring investigations and the hospitals carrying them out conform to all relevant Research Governance arrangements.
- Providing the medical technology companies sponsoring clinical investigations with consistent and explicit guidance on the NHS's approach to corporate management of medical device investigations by NHS hospitals.
- Avoiding the need for site-by-site review and re-negotiation of clinical investigation agreements. This has been found to be one of the greatest impediments to quick and efficient initiation of UK clinical investigations.

² Follett, B. & Paulson-Ellis, M. (2001) *A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior NHS and University Staff with Academic and Clinical Duties*. London: Department of Education

PART 2

Commentary on the structure and use of the model CIA

1. Development of the model CIA

A large number of stakeholder organisations have been involved in the development and review of the model CIA. These include the Departments of Health from England and the Devolved Administrations, NHS hospitals (including Foundation Trusts), the MHRA, the NHS Confederation, the ABHI, and medical device manufacturing companies. The intention has been to ensure that the text of the mCIA is consistent with that of previously published model agreements except where the circumstances of device investigations mean that different arrangements are necessary. It has been structured to meet the needs of the companies sponsoring the studies and the NHS bodies accountable for the patients participating in them. It should be noted that this mCIA is NOT intended for use in connection with investigations of in vitro diagnostic devices.

2. Voluntary use of the model CIA

The model CIA contains references to standards for the management and governance of commercial clinical investigations that are either mandatory or reflective of good practice. These include:

- EN ISO 14155, the harmonised standard for good clinical practice in clinical investigations of medical devices,
- ICH-GCP, the harmonised tripartite guideline for good clinical practice,
- the Medical Devices Regulations 2002 (and subsequent amendments) implementing the EU medical devices directives,
- the UK Research Governance Frameworks that are relevant to England and each of the Devolved Administrations (Scotland, Wales and Northern Ireland),
- patient indemnity arrangements (specifically the ABHI Compensation Guidelines and ABHI Form of Indemnity),
- accountability through NHS bodies' Chief Executives for clinical research involving NHS patients.

All the Departments of Health throughout the UK, organisations representing NHS hospitals, and the industry recommend the use of the unmodified mCIA the model for Clinical Investigation Agreements to cover contract commercial medical device investigations carried out in the NHS, involving NHS patients and resources. However, its adoption by any individual company or NHS body is at their own discretion. Either the sponsoring company or the management at the hospital site is at liberty to propose to the other party that there are changes to the core terms of the agreement, or the use of an entirely different contract template. However, if they choose to do so, they would have to be aware of the likelihood that very long delays would be likely in the initiation of the investigation, and that the revised agreement would not have been exposed to the same intensity of review from a variety of NHS and industry perspectives.

3. Contracting parties

- 3.1 In order to comply with research and clinical governance requirements, and establish the correct lines of accountability for the work of clinicians practising in the NHS, all commercial Contract Clinical Investigations involving subjects recruited by virtue of their being current NHS patients, carried out in NHS hospitals, must be governed by contracts between the sponsor and the NHS body responsible for the clinical care of the clinical investigation subjects, irrespective of the institution that employs the investigator. This includes the situation where, for example, the investigator's substantive employment contract is with a university and the investigator holds an honorary contract with the NHS body.
- 3.2 In no case should the sponsor of a clinical investigation enter into a contract with an individual employee of either an NHS body or a university in a personal capacity to undertake a clinical investigation involving NHS patients.
- 3.3 In connection with many clinical investigations, Contract Research Organisations (CROs) are appointed by sponsors to recruit and manage sites. In these cases, the mCIA should have a tripartite structure with the sponsor, CRO and NHS body as the contracting parties, along the lines of the CRO mCTA for pharmaceutical trials managed by CROs. A CRO mCIA, drafted to take account of differences in the roles of sponsor companies and CROs, is planned.

4. Applicability of the model CIA

- 4.1 The mCIA is designed for use in connection with pre- and post-market clinical investigations involving NHS patients undertaken in NHS hospitals, and human volunteer investigations where volunteers are NHS patients.
- 4.2 The mCIA is not designed for use in collaborative clinical research involving the NHS and industry. Some sponsors wish to involve investigators employed by trusts or universities collaboratively in the design and development of medical devices, or the planning and research design aspects of contract commercial investigations. Such input should either be provided under a separate contract from the clinical investigation itself, under a contract between the device manufacturer and the investigator's substantive employer (either trust or university), or, if the device improvement and evaluation is of a more iterative nature, the whole development and evaluation project should be under a collaborative research agreement.
- 4.3 The mCIA is NOT designed for use in connection with the following kinds of investigations:
- investigations involving human volunteers who are not NHS patients,
 - performance evaluations of in-vitro diagnostic devices. An IVD model Performance Evaluation Agreement (mPEA) drafted for use with these devices is being considered,
 - investigator-initiated collaborative commercial investigations that are not sponsored by the device manufacturer,
 - studies sponsored by charities, government departments or Research Councils, whether or not such clinical investigations involve NHS patients and whether or not they are carried out in NHS hospitals,
 - any Contract Clinical Investigations performed by private institutions with patients recruited independent of their treatment within the NHS. This will include, for example, independent practitioners (GPs) running investigations in private

facilities, when the subjects have consented in the knowledge that the investigation is outside the NHS.

5. Negotiation of an investigation-specific CIA based on the mCIA

Every time it is used, the mCIA will require completion of the information specified in paragraph 8 of this Guidance. References to “the CIA” hereafter refer to an agreement tailored for a specific clinical investigation.

6. The terms of the model mCIA

The content of the mCIA is designed to address comprehensively the relationship between the sponsor and the NHS body accountable for the patients taking part in the investigation. It has been modelled closely on the mCTA and its content. The following paragraphs provide an explanation and guide to interpretation of certain key terms included in the agreement.

Clause 1.1: Definitions

Clause 1.1 defines terms used repeatedly throughout the mCIA and they are capitalised in the text. Definitions are in most cases drawn from the mCTA and additional device-specific definitions draw on sources such as the Medical Devices Regulations or NRES Guidance. It should be noted that several definitions in the mCIA e.g. ‘Clinical Investigation’ are deliberately different to their conventional “regulatory” meaning to facilitate the structure of the agreement.

Key points to note in Definitions:

- Where the ‘Clinical Investigation’ is referred to, for example in ‘Clinical Investigation’, ‘Clinical Investigation Completion Date’, ‘Clinical Investigation Subject’ etc, this includes matters connected with the involvement of patients receiving either the device under investigation or any control intervention. Therefore, the full definition of “Clinical Investigation Subject”, as per EN ISO 14155, is a person recruited to participate in the Clinical Investigation as a recipient of the device under investigation or as a control.
- ‘Clinical Investigation’ can mean a study of either a CE Marked or non-CE Marked medical device either as a regulated clinical investigation or a post market clinical follow-up study.
- ‘Investigational Device’ can therefore mean either a CE Marked or a non-CE Marked medical device.
- ‘Instructions for Use’ means the product labelling, the instructions for use that accompany the device in its packaging, other instructions for use such as the surgical technique or user manual or video or other information supplied separately to inform the user of the appropriate and safe use of the device.
- ICH GCP is referenced in the definitions because some sponsors choose to follow ICH instead of, or in conjunction with, the harmonised standard ISO 14155 for their good clinical practice requirements. Both are equally acceptable.
- As the harmonised standard EN ISO 14155 2003 (which is available at: <http://www.bsi-global.com/en/Standards-and-Publications/>) is about to be revised, and there will be a transition period when either the previous or new version may be used, sponsors will need to specify in the Clinical Investigation Plan which version they are using.

- The term 'Notified Body' used in the definition of Regulatory Authority means a certification organisation which the national Competent Authority of an EU Member State designates to carry out one or more of the conformity assessment procedures described in the annexes of the Directives. The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK Competent Authority under the three Medical Devices Directives.

Clause 1.2: Amendments to laws and other documents referred to in the mCIA

This clause makes it unnecessary to refer throughout the mCIA to amendments which have been made or are made in future to laws, regulations etc, such as the Medical Device Regulations 2002.

Clause 2: Investigator and Investigation Site Team Members

This clause addresses the fact that while the contractor is the NHS Trust (or Health Board in Scotland etc), investigators have important responsibilities in relation to the investigation other than their clinical and scientific duties, that they need to be made aware of by the hospital. NHS hospitals must take appropriate steps to ensure that the investigator is aware of all his/her obligations under the CIA and agrees to abide by the requirements of Appendix 6. The CIA specifies a number of investigator obligations, many of which (e.g. 4.1, 4.11, 4.12, 4.15.5, 8.1, 8.2, 8.3, 8.4, Appendix 3 paragraph 5.4, Appendix 4 paragraph 6, and Appendix 6) are well-understood duties of investigators. Other investigator responsibilities (e.g. 2.4, 4.5, 4.9, 4.18, 7.1, 7.2, 9.4, and 9.5) may be less familiar. NHS bodies should bring all these responsibilities to the attention of investigators in the course of training in research governance. It is particularly important that investigators not *substantively* employed by NHS bodies (i.e. those who have honorary employment contracts to cover their work in the hospital) fulfil the obligation to inform their employer (usually an associated university) of their plans to participate in investigations, and secure their permission to do so (Appendix 6, paragraph b).

The investigator's identity and role is specified in the CIA and is central to the NHS hospital fulfilling the work specified in the CIA. The NHS hospital should incorporate the obligations of the investigator under the CIA in any employment contract or other contract under which the services of the investigator are obtained. Therefore, it would be prudent if each investigation on which he/she takes a leading role is included in his/her job plan. The NHS hospital may seek warranties to satisfy the conditions in Appendix 6.

Clause 2.2: Liaison between hospitals and other bodies employing Investigators and other Investigation Site Team Members

When the investigator (usually a medical academic) is substantively employed by a body other than the NHS hospital, the hospital's research managers must give the investigator's employer timely notification of the investigator's proposed involvement. The two organisations must liaise to identify and agree appropriate costs and overheads to be included in the investigation's financial schedule (Appendix 5)). Arrangements must be made for these amounts to be passed through to the university on their receipt from the sponsor.

Clause 3.2: Governance

Reference is made in this section to the 1996 version of the Declaration of Helsinki in order to maintain consistency with the model Clinical Trial Agreement, which similarly refers to this version of the Declaration. The decision not to refer to later versions of the Declaration was deliberate.

This clause also refers to investigations conducted as part of an Investigational Device Exemption (IDE), i.e. connected to an application for licensing by the US Food and Drug Administration (FDA). The mCIA has been negotiated to exclude any references to foreign laws so when it is necessary for a sponsor to ensure that its sites are compliant with specific US statutes, it is essential that sponsors notify hospitals, in writing, precisely what is required and make their own judgement about whether the site is compliant. The final sentence of clause 3.2 is NOT an invitation to sponsors to modify the mCIA by writing into the investigation-specific CIA any procedures required to ensure the hospital's compliance with the requirements of the FDA. In relation to the security of electronic records, for example, it would not be sufficient to specify, "compliance with section 21 of US CFR Part 11". In any event, the hospital should not be willing to warrant or give any other undertaking that they do comply with US law as they will not be familiar with it. The sponsor will apply whatever tests are available to it to judge whether the hospital is compliant.

Clause 3.5: Anti-corruption provisions

It has been suggested that arrangements for US FDA regulated investigations carried out under an IDE (referred to in clause 3.2), or any studies carried out under contract for a US-domiciled company, may need to meet the requirements of the US Foreign Corrupt Practices legislation if the data obtained is to be usable in submissions to the FDA. Some, but not all, US-domiciled companies have sought to include clauses covering this in clinical investigation agreements.

It has not been possible, in this first published version of the mCIA, to address the matter comprehensively and the issue is currently being actively considered. In the meantime it should be pointed out that the NHS comprises bodies set up under legislation and subject to varying degrees of control by the Secretary of State for Health. Research governance publications, in particular the NHS Research Governance Framework for Health and Social Care (version 2, April 2005) detail how NHS bodies prevent corrupt practices and outline sanctions imposed by regulatory bodies in the event of malpractice. Clauses 3.2, 3.4, 3.5, 4.11 and 4.15 of the mCIA make relevant provisions and clauses 10.1 and 14.3 provide that the fees and charges set out in the Agreement are the only amounts payable by the Sponsor to the site in connection with the investigation.

In addition NHS bodies may wish to make provision in Appendix 5 as follows -

"During the term of this Agreement and for a period of three (3) years after the final payment from the Sponsor has been made under it, the Trust shall permit the Sponsor and its auditors to have such access to records relating to the arrangements covered by this Agreement as they may reasonably require".

This would require the NHS body's financial records related to commercial contract research to be held in a form that allows them to be audited separately from its general finances. NHS Finance Rules governing Income Generation activities may require financial records to be held in this way in any event.

Clause 3.6: Inconsistencies in documents related to the Investigation

Because the Clinical Investigation Plan at Appendix 1 of the CIA sets out arrangements for the investigation across all countries and sites, in most respects, the precise terms of the Plan take precedence over any inconsistent wording in the CIA. However, in respect of four important clauses: 5 – Liabilities and Indemnities, 6 – Confidentiality, Data Protection and Freedom of Information, 8 – Publication and 9 – Intellectual Property, the terms set out in the CIA take precedence.

These precedence arrangements must not in any way undermine the obligation on investigators to undertake the investigation in compliance with the terms of the favourable opinion given by the Ethics Committee.

Clauses 4.2 and 4.3: Public registration of the Investigation

As set out in clause 4.2, a sponsor using the mCIA agrees to register investigations on a free, publicly accessible website within 21 days of the initiation of patient recruitment. This clause, together with clause 4.4 requiring sponsors to ensure that the analysis of the results of the investigation is posted on a free, publicly accessible website, addresses the Government's policy on permitting healthcare professionals and the public free access to information about research being undertaken in the NHS and involving NHS patients. This is to ensure that studies that involve NHS patients and the NHS are widely known about by professionals in the field, and patients (1) to reduce the possibility of studies being duplicated unnecessarily, and to avoid making unreasonable demands on other patients and potentially exposing them to unjustifiable risks; (2) to ensure all clinical investigations in a certain field can be analysed and reviewed together; and (3) to ensure that all clinical investigations are registered and reported; whether or not they are commercially successful. It also meets the WHO objective of ensuring that a complete view of research is accessible to all those involved in health care decision making, to improve research transparency and strengthen the validity and value of the scientific evidence base.

It is expected that most investigations will therefore be registered on a website such as www.ClinicalTrials.gov no later than 21 days after the initiation of patient recruitment. However, the Government recognises that the registration of medical device investigations on this timescale might in some cases harm the commercial value of the Investigational Medical Device or the commercial interests of the Sponsor. Therefore, limited periods by which registration may, if justified under a public interest test, be deferred have been agreed. The reasons for allowing optional deferred registration relate to the relatively short time that medical device development takes, in comparison to the development of new pharmaceuticals; the structure of the medical device industry; the process and information required for CE Marking; and the life cycle of medical devices. The contractual requirement to register investigations (and in due course publish analyses of results) is a new development in this industry. The time limits set out in the mCIA closely parallel the timings of the US scheme which implements the requirements of the Food and Drug Administration Amendments Act of 2007 (see: <http://prsinfo.clinicaltrials.gov/fdaaa.html>). In the UK, registration is made at times when, in the US, information held by www.ClinicalTrials.gov would be removed from the 'NIH lock box' and published.

The default requirement, set out in clause 4.2, is therefore qualified by clauses 4.3, 4.3.1 and 4.3.2 which set out the periods by which registration may be deferred in a number of specific circumstances. A flowchart summarising deadlines for registration is shown below. Sponsors are not expected to liaise with NHS bodies over the date of registration.

Clause 4.3.1 covers 'regulated' investigations, registration of which has been deferred for commercial reasons. This parallels the requirement for confidentiality imposed on national Competent Authorities by the Medical Devices Directives. If the investigation results in CE Marking of the device, registration must take place no later than 30 days after CE Marking. If the investigation does not produce data that allow CE Marking, the manufacturer is allowed a further period to carry out redesign, further investigation, etc of the device, but registration must take place no later than 24 months after the original Investigation Completion Date. In order to prevent indefinite deferral of registration, if for any reason the Investigation Completion Date is never reached, all investigations that are initiated and recruit patients must be registered no later than 36 months after the date for resolution of data queries specified on the Timelines in

Appendix 2 of the CIA. If the investigation is closed at any time because a safety issue arises, registration must take place within 21 days.

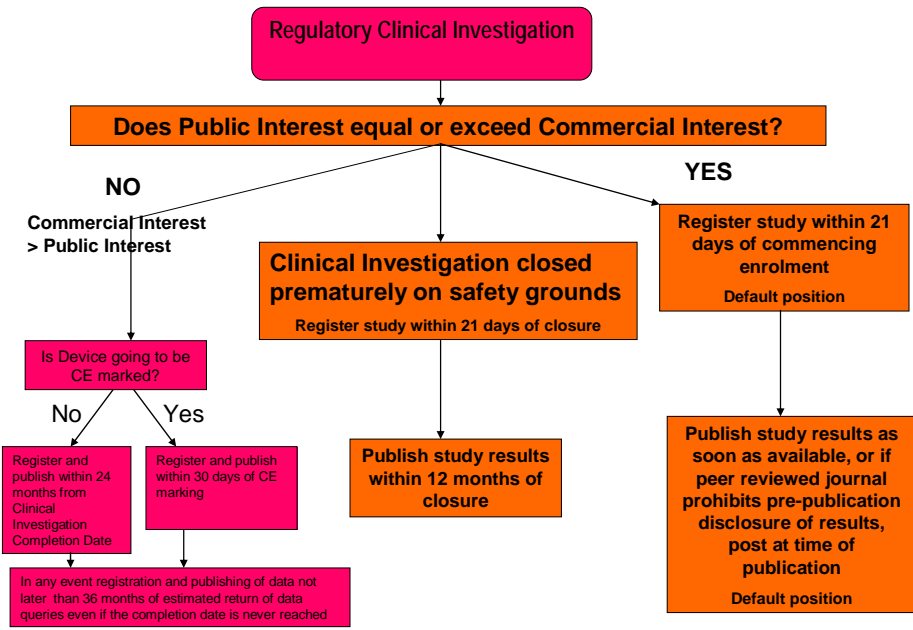
Clause 4.3.2 covers 'non-regulated' investigations, registration of which has been deferred for commercial reasons. The sponsor must register these investigations no later than 24 months after the Investigation Completion Date, or, as above no later than 18 months after the date for resolution of data queries specified on the Timelines in Appendix 2 of the CIA. If the investigation is closed at any time because a safety issue arises, registration must take place within 21 days.

It is not intended that pilot studies or small-scale feasibility studies of devices, that would have no independent scientific value, should be separately registered and results arising from them published if they are part of a larger programme evaluating a novel device. However, even small-scale stand-alone studies should be registered and results obtained from them should be published, and they should also be registered, and information about them posted on a results database if they are stopped as a result of safety concerns.

Sponsors planning to contract with NHS hospitals to carry out clinical investigations and at the same time considering exercising their option to defer registration will need to consider carefully the public interest in early registration and balance that against any concerns that registration on the usual timescale might do serious commercial harm to the device under investigation. They should only defer registration if they judge that their commercial interest in confidentiality outweighs the public interest in disclosure. If they opt to defer disclosure, they should keep that decision under review throughout the course of the investigation, as the balance of public and commercial interest may change, and they should register the investigation as soon as they judge that the public interest outweighs the commercial interest. They should record their analysis of public vs commercial interests so that there is an audit trail covering their decisions relating to registration.

Sponsors will need also to be aware that the NHS body hosting the investigation and the reviewing Ethics Committee are subject to the Freedom of Information Act (FOIA) and may be the recipient of questions about its portfolio of medical device investigations. On receipt of an enquiry covering the clinical investigation, the NHS body would notify the sponsor according to clause 6.2.7 of the mCIA and consult with them, in accordance with all applicable guidance, in relation to whether information requested was covered by one of the exemptions. As the information required for registration of the investigation might be the same information that might be requested under FOIA, sponsors proposing to defer registration should consider whether their analysis would pass the 'public interest test'.

Registration and Publication of a Regulatory Medical Device Clinical Investigation

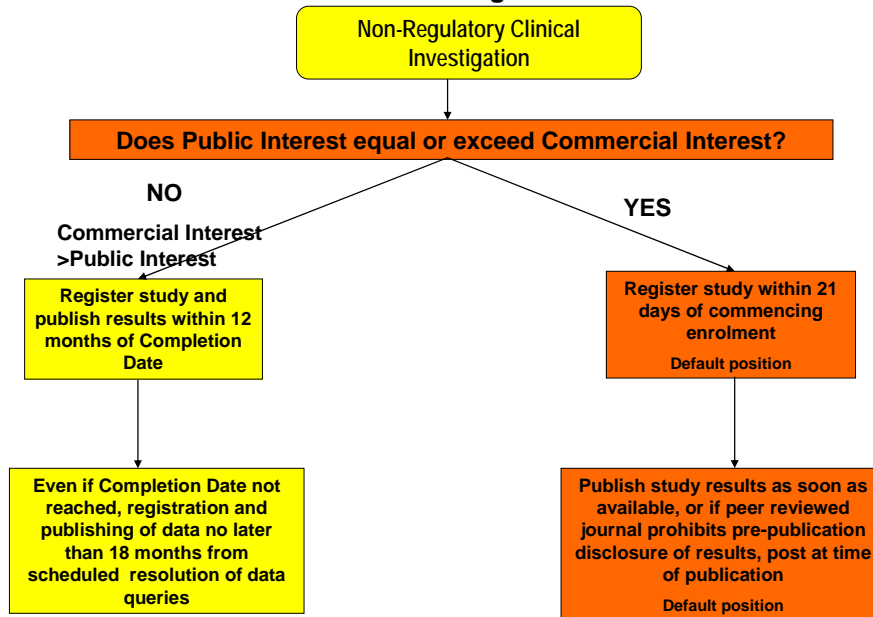


Clause 4.4: Publication of the analysis of the results of the investigation

Once again, as for registration of investigations, there is public interest in the results of investigations, and these should be available to healthcare professionals and the public, whether or not a study is published in the medical academic literature. This requirement ensures that all clinical investigations in a certain field can be analysed and reviewed together. It also ensures that the headline results of all clinical investigations are reported, whether or not they are commercially successful. A flowchart summarising deadlines for publishing results of investigations is shown below.

Clause 4.4.1 covers ‘regulated’ investigations and clause 4.4.2 covers ‘non-regulated’ investigations. The deadlines for publishing analyses of the results of these categories of investigations closely parallel the timescales for registering investigations set out in 4.3.1 and 4.3.2 and explained above. Recognising that many journals will not publish articles that have been pre-empted by earlier release of results, there are provisions to allow some delay while peer reviewed publications are being made, but also ‘backstop’ provisions to prevent the indefinite deferral of results being posted.

Registration and Publication of a Non-Regulatory Medical Device Clinical Investigation



Clause 4.5

Registration and publication as per clauses 4.2, 4.3 and 4.4 are sponsor responsibilities and neither investigators nor trusts should undertake them. However, trusts should follow up the trial, even after their role in it has been completed and ensure that sponsors comply with their obligations under the CIA. Clauses 4.3, 4.4 and 4.5 survive the termination of the Agreement.

Clause 4.6: regulatory aspects of medical devices investigations

Guidance on the role of MHRA and the National Research Ethics Service in relation to device investigations, and categorisation of investigations is available at: <http://www.nres.npsa.nhs.uk/rec-community/guidance/#medicaldevices> and <http://www.mhra.gov.uk/home/groups/es-era/documents/publication/con007504.pdf>

Clauses 4.7 and 4.8

One of the objectives of developing the mCIA is to facilitate the initiation of investigations. The availability of signatories can lead to delays, and there are advantages to investigation contracts being signed off as soon as their investigation-specific terms are finalised. This would be before a Letter of No Objection has been obtained from the MHRA (where needed) and before a favourable opinion has been obtained from the ethics committee. However, it is crucial that the investigation does not start before those approvals (where necessary) have been obtained. To provide reassurance to the hospital that signing the agreement before the approvals have been granted will not create a risk of investigation initiation occurring too early, clause 4.7 requires Sponsors to delay supply of the Investigational Medical Device to the site until it has received all approvals. Clearly this requirement does not apply to situations where the CE Marked investigational device is already in use at the site as part of normal care. Similarly, there is an obligation on the hospital to ensure that no non-routine clinical interventions mandated by the Protocol take place before receipt of final, written ethical and regulatory approval, when it is required.

Clause 4.9: Changes to the Clinical Investigation Plan

When substantial amendments are made to the plan and approved by the REC where necessary, it is important that they are implemented expeditiously. Liaison between the investigator and the sponsor is the most efficient way to ensure this. However, without involvement and approval of the R&D Office, it could also create a risk that the financial or service implications of the change might not be recognised or appropriately reflected in a change in the financial schedule. Therefore, provisions have been negotiated that allow the investigator to sign off and implement the change (clause 4.9), but require the sponsor simultaneously to initiate the 'change protocol' procedures set out in clause 14, and in due course reach agreement on a new financial schedule. As substantial changes are mandatory for the site, the investigation would have to be terminated if the site were unable to accommodate them.

Clause 4.11: Financial disclosure

In the case of clinical data that will also be provided to the US Food and Drug Agency for licensing under the US regulatory system, financial disclosures are required to be made by the investigator under FDA rules. Because the relevant US laws are not written into the contract, the sponsor must specify to the investigator what disclosures are necessary.

Clauses 4.11 and 4.12: Recruitment

Prior to agreeing the target numbers of patients to be recruited, the investigator should, in collaboration with the R&D Office, undertake an assessment of the feasibility of the investigation at the site. This should take account of the predicted availability of patients meeting inclusion and exclusion criteria and access to all support services required under the Plan. Focusing effort on the practicalities of participation in the investigation helps to ensure that the recruitment target is realistic and that the timelines (as inserted in Appendix 2) can be met. In order to emphasise how seriously hospitals should attempt to fulfil the recruitment target, they are required by clause 4.13 to use their 'best endeavours'.

Some Clinical Investigations undertaken by NHS Trusts will be multinational with competitive recruitment. If recruitment is proceeding slowly and the target number of subjects specified in clause 4.13 is not being achieved, clause 4.14 permits the Sponsor to scale back the target to allow other sites to fill the gap, and conversely, if recruitment is ahead of target, a higher number of subjects may be allowed to enter the Investigation. The NHS Trust is not, however, under an obligation to recruit more than the target number specified.

Clause 4.15.6: Training

NHS bodies should provide training to researchers under research governance arrangements and this should certainly include familiarisation with the requirements of ICH GCP. The sponsor decides whether to manage the investigation under ICH GCP and/or under the harmonised standard EN ISO 14155. If the latter is the case, they may need to provide training to NHS staff involved in the investigation. The need for additional training for participation in the investigation should be considered during the costing of the investigation.

Clause 4.18: Competing Investigations

Hospitals' R&D Offices should, through their knowledge of their research portfolio, be aware of any potential for conflicts to arise involving recruitment to competing Investigations. These possibilities should be discussed with investigators and the R&D Office should not proceed with arrangements for Investigations that might prejudice the Trust's ability to perform existing contractual obligations. However, the primary

obligation of hospitals is the care of their patients, so this obligation (like several others in the agreement, such as clauses 2.3 and 3.5), is qualified by an over-riding duty to consider the best interests of patients.

Clause 5: Liabilities and Indemnities

Clause 5.1 concerns the standard Form of Indemnity for medical device investigations the terms of which should not be modified in any way by either NHS bodies or sponsors. NHS bodies should regard the provision of this Form of Indemnity, together with the sponsor's commitment to operate the ABHI Clinical Investigation Compensation Guidelines (referred to in clause 3.3) as essential for their participation in the investigation. The Compensation Guidelines include 'no-fault' compensation which is standard in the UK but unusual in a number of countries such as the US, from where many sponsor companies originate. No-fault cover means that the sponsor agrees that a Clinical Investigation Subject who, on the balance of probabilities, has been harmed by participation in the study, would receive compensation comparable in scale to what would be offered by an English Court, without the patient needing to prove fault on the part of the sponsor. Sponsors must agree to these arrangements even though they may mean that the sponsor's usual clinical trials insurance arrangements need reorganising.

Clauses 5.4 and 5.5 relate to non-clinical liabilities that may arise out the research. A sponsor's liability to the hospital undertaking the trial is unlimited. NHS hospitals' non-clinical liabilities in relation to research are not usually covered by NHSLA-administered schemes and it is unlikely that either their Boards, or in the case of English Foundation Trusts, the regulator (Monitor) would authorise their taking on unquantified and potentially unlimited liabilities, such as might arise from an expensive Intellectual Property Rights claim. Therefore, hospitals' liabilities to sponsors have been capped under this agreement, and the caps are set at two different levels depending on the nature of the breach. The first cap, in clause 5.4, covering most liabilities, is set at an amount not exceeding the total value of the contract. The second level of cap, in clause 5.5, covers claims by the sponsor arising from (a) wilful and/or deliberate breaches of the agreement and (b) any breach related to clauses 6 (Confidentiality, Data Protection and Freedom of Information), 8 (publication) and/or 9 (Intellectual Property). This provides for the hospital's liability to be limited to an amount not exceeding twice the value of the contract. The contract value would be the total payments to be made by the Sponsor to the hospital if all the target number of patients were recruited. It is recognised that for a number of possible types of breach (for example, the loss of important Intellectual Property Rights or the release of strategically important information) these provisions might not fully compensate the Sponsor to the extent of their loss. However, amounts equal to the value of the contract or twice the value of the contract would represent significant losses in terms of trust R&D finance. Under research governance, research managers are required to ensure that research staff are aware of the importance of confidential research information. The possibility of having to pay compensation on the basis negotiated would be an additional incentive to encourage hospitals to take every reasonable precaution to prevent a breach. These precautions could include: having in place robust research governance arrangements; instituting training programmes for researchers undertaking commercial investigations; publicising to researchers and their staff the crucial importance of protecting the integrity of Sponsors' confidential information; and taking disciplinary action in the event of a wilful or reckless breach of the provisions of clinical Investigation agreements.

Clause 5.6: Insurance

Sponsors must provide evidence of insurance cover, or provide an indemnity covering their potential liabilities to subjects participating in the Investigation. Sponsors are not required to take out clinical investigations insurance, but RECs and hospitals will wish

to be assured either that sufficient insurance cover has been purchased considering the risks posed by the investigation, or that the sponsor has provided an evidence of an indemnity from another organisation. So-called 'self-insurance' is neither insurance nor an indemnity, and is not a satisfactory way of meeting the need for secure finance underpinning the sponsor's obligations to hospitals and patients. Hospitals and the Research Ethics Committees that provide an opinion on the investigation proposal may therefore take a view as to the indemnity and/or the adequacy of their clinical investigations insurance, in relation to the risks posed by the specific investigation.

Insurance policies specify *maximum* cover (the maximum amount that the insurer might have to pay) whereas the hospital and REC needs to know the *minimum* cover that is available. These figures can be the same amount but the hospital needs the figure to be specified as the minimum; it is only concerned to know how much compensation is guaranteed being covered by insurance. Sponsors should note that the amount of insurance cover does not limit their liability as the sponsor of the investigation and higher liabilities would have to be met from their own resources. Trusts should be vigilant in assessing the potential risk represented by the interventions and be aware of the possibility of compensation claims arising that would not be covered by insurance cover.

Clause 6: Freedom of Information

Clause 6.2.8a makes it clear that under the FOIA, public bodies cannot be constrained in deciding whether to provide the information requested, though under clause 6.2.8b, they agree to consult the sponsor in accordance with all applicable guidance, for a view as to whether an exemption applies.

Clauses 6.2.8b and 6.2.9 include periods of time that are different from those in the mCTA used for pharmaceutical trials. This is to allow smaller medical device manufacturers, who are unlikely to have direct access to in-house legal advice, time to take appropriate advice, particularly in the event that they might consider taking legal action to prevent the disclosure of information by the hospital.

Clause 8: Publications

The model CIA recognises that hospitals in the UK have a responsibility to ensure appropriate publication and dissemination of clinical research for the benefit of patients and their peers. Publication should be done in an orderly way, usually in compliance with the publication policy set out in the Clinical Investigation Plan. In line with clause 3.6, however, clause 8 takes precedence over any publication policy set out in the Plan. The term publication covers any type of public presentation, whether it is written or oral.

This clause sets out conditions governing the way that individual investigators should prepare their publications, and the opportunities they should allow sponsors to comment on them. It also specifies the window of opportunity available to sponsors in which they can protect proprietary information. This clause was drafted to ensure that publications based on limited and perhaps unrepresentative data from one or a limited number of sites do not inadvertently misrepresent results, by requiring that the principal report(s) of each clinical Investigation are published before articles based on sub-sets of the data. The terms of the mCIA allow publication of a dissenting interpretation of the clinical Investigation's data after the principal reports have been published, provided the procedures in Clause 8 of the mCIA are adhered to. The provisions set out in clause 4.4 relating to results publication raise the possibility of up to a 36 month delay in publication in certain circumstances. Although this might affect investigators academic publication plans, it would be likely to happen in only the rarest circumstances.

Clause 9: Intellectual Property

As stated in paragraph 4.2, above, the mCIA should not be used as a template for contracts covering investigators' or other trust staff's involvement in the development of medical devices, or their involvement in the planning and research design phase of commercial investigations.

The principles underlying the drafting of the IP clauses are firstly, that each party retains ownership of any pre-existing IP or Know How owned by it or licensed to it. Secondly, any IP or Know How generated at the Investigation site that relates to the Clinical Investigation Plan or the Investigational Medical Device (on its own or in combination with other medical devices or drugs) is the property of the Sponsor. Thirdly, clinical procedures and related improvements are the property of the site and depending on the inventor's employer (hospital or university), could be protected and exploited accordingly. Fourthly, the site also has the right to use Know How gained in the course of the investigation in its normal clinical work, provided it does not result in disclosure of the Sponsor's confidential information. These provisions are designed to protect the Sponsor's IP and give the Sponsor ownership of anything derived from it, but allow the investigator's employer to protect and exploit clinical procedures and related improvements and to use Know How generated while the Investigation is being undertaken.

Clause 9.3 does not give the sponsor ownership of all IP subsequently generated by the investigator or their team in the research field of the investigation. It is not intended that participation in an investigation involving a particular device would prevent an investigator's institution owning the IP associated with a different device to serve the same purpose, provided that the design of the new device did not result from the investigator's privileged access to the sponsor's confidential information. In such a case, the investigator should discuss ideas for the new device and its evaluation with the sponsor, or other manufacturers, under a Confidential Disclosure Agreement, with the intention of initiating collaborative research or exploiting the invention commercially.

The Clinical Investigation Plan should be explicit as to what information, including user-preference information, is to be provided by the investigator involved in the study. Investigators supplying such information, if it is of value to the future development or modification of a device should not expect to profit from it.

Clause 10 and Appendix 5: Financial arrangements

A financial schedule must be negotiated for each Clinical Investigation. This should cover all financial issues related to the Investigation Site including the costs associated with medical, scientific and nursing staff, and the costs of all services (apart from the costs of routine care) including clinics, hotel charges (e.g. bed days), laboratories, imaging, medical records, pharmacy services etc where needed.

Clinical Investigations should be costed in keeping with NHS requirements and use of the Costing Guidance published by UKCRN is recommended. This is published at <http://www.ukcrn.org.uk/index/industry/costing>

The Sponsor should consider supplying non-CE Marked devices used in clinical investigations, which by definition cannot be marketed, free of charge to the hospital, although this is not a UK requirement. Payment for CE Marked devices for use in investigations may be negotiated relative to the costs of existing supplies of devices for the same indication and their use should be cost-neutral, although again, this is not a UK requirement. Sponsors may only be charged for costs (research costs and the costs of clinical services, including service support and excess treatment costs), that

are *additional* to the costs that the NHS would have incurred in the normal course of the care of the patients in the clinical Investigation.

The financial and other interests of universities that employ investigators involved in clinical investigations should be recognised by hospitals as required in clause 2.2 of the mCIA. The notification arrangements noted are designed to ensure that universities have the information needed for the protection of their interests. There should be formal agreement between hospitals and universities, covering their entire clinical investigations portfolio, setting out processes for the identification of the university's direct and indirect costs and overheads, and the apportioning of research income between the institutions. This issue could be covered in the partnership agreements between hospitals and associated academic institutions that are negotiated in the process of implementing research governance arrangements. In the case of investigations for which the investigator's or site team members' substantive contract is held by a university, the university should be involved in the calculation of staff costs for the investigation and the NHS research managers should agree the content of the financial schedule with the university. Appendix 5 suggests text that should be included in the schedule in these cases.

There should NOT be separate financial arrangements between the sponsor and any hospital departments such as the pharmacy or the university that employs an investigator.

The staging or scheduling of payments should be negotiated, including any payments to be made before initiation of the investigation or any clinical intervention mandated by the Investigation Plan, (e.g. site set-up costs) and whether such payments are refundable or non-refundable.

Payments made by Sponsors to NHS bodies carrying out contract commercial clinical investigations are subject to VAT. Invoicing arrangements should be via the hospital Finance Department using formal VAT invoices in compliance with NHS Standing Financial Instructions.

Changes to the Clinical Investigation Plan required by the Sponsor should be negotiated as set out in Clause 14 and a revised Financial Schedule signed by the Parties and attached to the agreement.

Clause 12.4: Early termination

A number of specific grounds for early termination of the investigation at the site are set out in Clause 12. Even when a site is recruiting at the rate required in the CIA, over-recruitment by other sites and early achievement of the total numbers of Clinical Investigation Subjects required under the Clinical Investigation Plan may create circumstances in which early termination of recruitment at the site is unavoidable. Clause 12.4 explains the sponsor's obligations in such circumstances.

Clause 14.2: Changes to the Clinical Investigation Plan

The procedure to be followed when 'substantial' changes are made is set out in Clause 14.2 and if these require a revised Financial Schedule this should be agreed, signed by the Parties and attached to the Agreement.

Clause 15: Force Majeure

The parties will agree a reasonable time limit after which delays due to an act of God etc affecting one party's performance of their duties allow the unaffected party to terminate the contract.

Clause 19: Dispute resolution

If a dispute arises between the parties to the mCIA, they are required, in the first instance, to attempt to resolve any dispute by way of mediation. An informal local procedure is specified, escalating if necessary through more formal processes. If mediation fails, the parties can take the dispute to the Courts of the jurisdiction in which the site is located.

Clause 20: Signatures

The signatories to the CIA will be the authorised representatives of the sponsor and the NHS body. In the case of the NHS hospital, the signatory must have legal authority to bind the NHS Trust. This might be the Chief Executive, the Director of R&D or the Director of Finance.

The investigator is not to be a signatory to the CIA, which is between the corporate bodies. As provided in Clause 13.1, the NHS body takes on responsibility for the acts and omissions of its sub-contractors. These include the warranties relating to the investigator given by the hospital in Appendix 6 to the agreement. The NHS hospital should keep on file a copy of Appendix 6, signed by the investigator, at the initiation of each investigation. The Sponsor may require the investigator to sign a copy of the Clinical Investigation Plan and the investigator will be the applicant for the purposes of ethical approval of locality issues.

Appendix 2: Timelines

The milestones included in the Appendix are by way of example and the parties may amend the list as they see fit. However, for the purposes of clauses 4.3 and 4.4 it is important that a reasonable date is specified for the resolution of all data queries.

Timelines will require early negotiation involving the investigator and the sponsor. It will be particularly important that they are realistic with respect to the date that the Clinical Investigation Plan will be finalised, and should build in as footnotes, contingency plans for changes in the event that there is delay in, for example, regulatory or ethics committee approval. The shared responsibilities indicated on the table in Appendix 2 show that the timing of some events is dependent on good co-ordination between the Investigation Site and the sponsor e.g. in scheduling all participants' availabilities for the initiation visit. Pursuant to GCP, the responsibility for local ethics committee submission lies with the Investigation Site but it is recognised that in practice assistance is often provided by the Sponsor and accordingly parties may wish to assign shared responsibility in relation to this milestone.

PART 3

Information needed to develop the site-specific CIA

Title page: Name of the Clinical Investigation, names and addresses of NHS hospital and Sponsor

Second recital: Define the disease/intervention field with which the investigation is concerned.

Fourth recital: Define the disease/intervention in which the NHS Trust has expertise.

Fifth recital: Insert the title of the Clinical Investigation and Sponsor's unique investigation identifier.

Clause 1.1: Insert the Sponsor's unique investigation identification number in the definition of "Clinical Investigation".

Clause 1.1: Insert the legal name of the NHS hospital in the definition of "Trust" or "Board" (Scotland).

Clause 2.1: Insert the name of the investigator.

Clause 4.6.5: Insert the name of the Research Ethics Committee (or Committees in the case of multi centre trials).

Clause 4.13: Insert the number of Clinical Investigation Subjects.

Clause 5.6: Insert the amount of clinical investigation insurance cover held by the Sponsor to cover the investigation. The amount must be appropriate to the level of risk involved in the Investigation.

Clause 16: insert the addresses to which notices should be sent.

Appendix 1: Attach the Clinical Investigation Plan and any amendments made before signature of the Agreement.

Appendix 2: Add target dates.

Appendix 5: Insert a copy of the Financial Agreement.

Appendix 6: The investigator should sign a copy of Appendix 6, which should then be kept in the project file

DH and ABHI advice and assistance

The Research and Development Directorate of the DH and the ABHI can be contacted on the use of the model CTA and this guidance.

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