A model Confidentiality Disclosure Agreement (mCDA) template, for use during the early set-up of commercial contract research in NHS organisations

Developed in partnership by:

The NHS R&D Forum, Contracts Working Group

Health & Care Research Wales

Health Research Authority

HSC Northern Ireland

NHS Research Scotland

Document Control

This document, Final Version 1.0, February 2022 is issued and updated in partnership.

Readers should ensure that the latest version is being viewed which is available on the IRAS Website

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1. Background

Confidentiality Disclosure Agreements (CDAs) (sometimes called non-disclosure agreements or NDAs) are legal agreements that are often used in commercial contract research to govern the sharing of confidential information from the commercial sponsor to the prospective participating NHS organisations[1] prior to execution of the site agreement (e.g. mCTA, CRO-mCTA, mCIA, etc.). In some cases, sponsors request that an NHS organisation enters into a CDA prior to or during the site selection process and in other cases only once the site has been selected and site set-up activities have commenced. This inconsistency of approach, together with the historic absence of UK template agreements, has resulted in wasteful confusion and delay.

Commercial Contract Research is different to collaborative research or investigator-initiated research supported by commercial sources of funding, for which other arrangements are more appropriate. The mCDA is intended only to cover the provision of confidential study information from Sponsor/Clinical Research Organisation (CRO) to NHS organisation during the feasibility/site set-up phase of Commercial Contract Research.

Given the historic absence of a UK template mCDA and the proliferation of sponsor/CRO specific agreements, NHS sites have expressed a lack of confidence in understanding and managing the impact of certain clauses, which is particularly true for (but not exclusive to) smaller teams that do not have access to experienced contracts management expertise. Staff may act with risk-aversion (not signing the agreement), or reluctantly accept inappropriate terms for the organisation concerned (signing reluctantly and inappropriately).

NHS R&D Forum Members, including experienced contracts teams, have also reported concerns that the burden of managing an increasing number and variety of CDAs is becoming too onerous and negatively impacting on efficiency of study set-up in some cases. We had also heard the same concerns from industry colleagues.

This model CDA template has been produced by a UK-wide partnership. We aim, using these documents, to help make the early sharing of information, for feasibility and site set-up purposes, clearer, more consistent, and efficient in line with the UK Vision for Clinical Research Delivery[2].

[1] Throughout this document references to NHS should be construed to include reference to Health and Social Care (HSC) in Northern Ireland

[2] The Future of UK Clinical Research Delivery

2. Introduction

The template has been developed by the UK Four Nations Contracting Leads Group and the NHS R&D Forum contracts working group, which is a group of lead NHS research contracts managers. Commercial Sponsors and Clinical Research Organisations have reviewed and fed into the process, such that we believe this to be a well-developed agreement for the purpose of early sharing of study level information for commercial contract research.

3. Sharing study information early for quick feasibility assessment

For Sponsors of clinical research to talk effectively with a potential participating NHS organisation about whether to run a study at that organisation, it is necessary to share information quickly between the two. The information required to facilitate early conversations about general feasibility is usually provided to ensure that it is worth the organisation progressing to site selection, when full assessment and arranging of capacity and capability can occur. At the earlier stage the information provided to NHS organisations may not always be commercially sensitive in nature, but Sponsors may wish to share confidential information and a Confidential Disclosure Agreement (CDA) may be signed.

The use of CDAs for the set-up of Commercial Contract Research at NHS organisations can become bureaucratic and protracted for all parties, causing delays that do not serve science or patient care.

We have therefore developed this model template CDA agreement (mCDA) for use to prevent lengthy negotiations, to ensure that that the rights and obligations of all parties are appropriate and that they can be consistently met by the prospective participating NHS organisation.

4. A study-specific template for good governance and speed

This recommended template is a resource Sponsors can/should choose to use with NHS/HSC sites. Doing so will reduce negotiation time with sites, provide assurances to both parties that their rights and responsibilities are appropriate and facilitate compliance by sites with contract terms, replacing the inconsistency of terms to which NHS organisations are currently subject.

This is a single model template providing basic study-specific identifiers to NHS organisations and which, if left otherwise unamended, should be simple,

straightforward, and swift to execute. It covers the sharing of confidential information by the Sponsor to support early feasibility discussions, site selection and set-up up to the point that a study site agreement (e.g. mCTA) is executed. It also covers confidential information that has been shared if the study at the NHS organisation does not progress to site agreement.

The template created is study specific rather than a master or generic agreement. Used without modification, it allows for rapid agreement and the provision of study level information in an efficient and consistent process. Agreeing an unmodified mCDA should not be considered an extra step compared to use of a master agreement, which to function effectively requires variation each time a new study is added, prior to study specific information sharing. It is not acceptable to the NHS to use master agreements that do not require the disclosing party to propose, and the receiving party to accept, the inclusion of new study proposals within the terms of the agreement. Such agreements would place obligations and liabilities upon the NHS without fair notification that such obligations and liabilities exist and cannot be appropriately managed.

5. Authorised signatories

Sponsors are reminded to ensure that all contracts are sent for organisational authorised signature, usually through the R&D office, and not the study team. Sites are asked to make details of the route-to-signature clear, visible and available for Sponsors and to consider ensuring signatories for the mCDA are within the R&D office or other enabling function to facilitate sign-off as quickly as possible.

Sponsors should be aware that provision of alternative CDAs, or modifications to the mCDA, will be subject to review and potentially significant delay.

6. Additional NHS-specific mechanisms for managing confidential information

Sponsors can further be assured that the NHS in the UK has a number of mechanisms in place to ensure that the confidential information it receives is managed appropriately, within or outside of the context of a CDA.

These mechanisms are in addition to the current legal framework and to the contractual protections subsequently provided should the partners enter into a study site agreement. These include:

- **NHS policy**
  Confidentiality NHS Code of Practice, (2003)[3], The Records Management

[3] Confidentiality: NHS Code of Practice

Code of Practice for Health and Social Care (2016)[4], NHS Information Governance - Guidance on Legal and Professional Obligations, (2007)[5], The 'Information Security Management: NHS Code of Practice (2007)[6], UK government data security standards 'Your Data: Better Security, Better Response, Better Care' (2017)[7], NHS Scotland Code of Practice on Protecting Patient Confidentiality (2012)[8]

- **NHS Employee Duty of Care**
  NHS employees have a duty of care to their employer, usually explicit within their contract of employment, to retain information securely.[9]

- **Study Site Agreements**
  If an organisation is selected and confirmed, participation in clinical research will be governed by a subsequent agreement between the Sponsor and the site (for example, the mCTA). Such agreement supersedes the CDA. All model templates can be found on the IRAS website Integrated Research Application System.

- **Training & good practice**
  NHS staff receive training in the management of confidential information for patient care.

Early contact with NHS R&D departments is always encouraged before site selection. All NHS R&D offices are listed on the NHS R&D Forum website NHS R&D Forum

7. Scope of the model CDA

This template covers the sharing of study information for commercial contract research only.

Any consultancy work to support a Sponsor company in developing a protocol, for example with the input from a Key Opinion Leader (KOL), is outside of its scope.

The template does not cover the sharing of personal data.

[4] Records management: code of practice for health and social care
[5] NHS information governance: legal and professional obligations
[6] Information Security Management: NHS Code of Practice
[7] New health data security standards and consent/opt-out model
[8] Revised Code of Confidentiality Final
[9] NHS England report template

8. Model Template Agreement (separate attachment)

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9. Contacts for queries and feedback

The mCDA is published for consultation in use. Should you wish to send feedback or ask a question about the template please contact the 4 nations contract leads as follows:

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

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

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

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

All queries may be subsequently passed onto the NHS R&D Forum contracts working group at info@rdforum.org.uk