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

Supported by:

National Institute for Health and Care Research

Document Control

This document, Final Version 2.1, March 2023 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 (for example the model clinical trial agreement (mCTA), clinical research organisation mCTA (CRO-mCTA), or the model clinical investigation agreement (mCIA)). 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 significant 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 model CDA (mCDA) is intended only to cover the provision of confidential study information from a Sponsor or 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 organisations 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. The recent Tickell review[2] and the ABPI's report Rescuing patient access to industry clinical trials in the UK[3] both highlight and reiterate the concerns raised by NHS R&D Forum Members.

This mCDA 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[4].

[1] Throughout this document references to NHS should be construed to include reference to Health and Social Care (HSC) in Northern Ireland
[2] Tickell review
[3] Rescuing patient access to industry clinical trials in the UK
[4] 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 CROs have also 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. The template is maintained by the UK Four Nations Contracting Leads Group.

3. Scope of the model CDA

This template covers the sharing of companies' confidential study information for commercial contract research only. The template does not cover the sharing of personal data.

Non-commercial Brunswick Agreements are available for non-commercial research.

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. Agreements to support consultancy work are available from the Lambert Toolkit.

4. Sharing study information early for quick feasibility assessment

For Sponsors or CROs 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 and CROs may wish to share confidential information and a 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 the rights and obligations of all parties are appropriate and that they can be consistently met by the prospective participating NHS organisation. This includes the liability of NHS organisations in ensuring that their employees and other Agents are compliant with the requirements of the agreement, in line with clause 3.3.

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

In the template and this guidance, Company is used to mean either the Sponsor or its appointed CRO which is a party to the agreement.

Companies should use this template with NHS organisations. Doing so will significantly reduce negotiation time between parties, 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, will be simple, straightforward, and swift to execute. It covers the sharing of confidential information by the Company to support early feasibility discussions, site selection and set-up up to the point that a subsequent agreement (for example mCTA) is executed. It also covers confidential information that has been shared if the study at the NHS organisation does not progress to any subsequent agreement.

Whilst the CDA covers sharing any documents which should be treated as confidential, it is good practice to mark such documents as confidential in nature (for example through the addition of a watermark). Companies may go further than this and include additional disclaimers within documents themselves.

The Agreement does not include, expressly or by implication, any representations, warranties or other obligations by the Discloser as to the fitness of purpose to the Recipient of any of the Confidential Information; or the accuracy of the Confidential Information which is provided to the Recipient in good faith; nor does the Agreement include, expressly or by implication, any representations, warranties or other obligations by the Discloser to grant any licence or rights to any of the Confidential Information or under any intellectual property rights except as expressly stated in the Agreement; disclose, continue to disclose, or update any Confidential Information; or negotiate, continue to negotiate, or enter into any further agreement with the Recipient.

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.

6. Authorised signatories

Companies are reminded to ensure that all contracts are sent for organisational authorised signature, usually through the R&D office, and not the study team. NHS organisations should make details of the route-to-signature clear, visible and available for Companies to facilitate sign-off as quickly as possible. Proposed investigators are not party to this agreement because their employing NHS organisation takes overall responsibility for their employees' actions in line with clause 3.

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

7. Additional NHS-specific mechanisms for managing confidential information

Companies 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 subsequent agreement between the Sponsor and NHS organisation (for example the mCTA). These include:

- **NHS policy**
  Confidentiality NHS Code of Practice, (2003)[5], The Records Management Code of Practice for Health and Social Care (2021)[6], NHS Information Governance - Guidance on Legal and Professional Obligations, (2007)[7], The 'Information Security Management: NHS Code of Practice (2007)[8], NHS Scotland Code of Practice on Protecting Patient Confidentiality (2012)[9]

- **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.

- **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.

[5] Confidentiality: NHS Code of Practice
[6] Records management: code of practice for health and social care
[7] NHS information governance: legal and professional obligations
[8] Information Security Management: NHS Code of Practice
[9] Revised Code of Confidentiality Final

8. Change history

Summary of key changes in March 2023

General

Template updated to be suitable for all studies with a commercial sponsor, and not just limited to clinical trials.

Parties

Registered address of the Company and Recipient Organisation to be included on page 1.

Clauses

Clarifying the definitions of Affiliate and Confidential Information.

Addition of a definition of Agents, and subsequent clarification of this within relevant clauses throughout.

Addition of a definition for the Environmental Information Regulations (EIRs), and clarification in clauses as relevant when the EIRs apply.

Addition of a definition for the Freedom of Information Acts (FOIAs), and clarification in clauses as relevant when the FOIAs apply.

Clause 5 – clarifying where the Company, not the Sponsor, is the contact point and / or responsible for activities.

Clause 13 – clarification of remedies available within different UK nations for breach of the agreement.

9. Contacts for queries and feedback

The mCDA is reviewed every 6 months based on feedback received. 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