Guidance on the use of the UK template Confidentiality Disclosure Agreements: model Confidentiality Disclosure Agreement (mCDA) and model Master Confidentiality Disclosure Agreement (mMCDA)

Developed in partnership by:

The NHS R&D Forum, Contracts Working Group

Health & Care Research Wales

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HSC Northern Ireland

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Document Control

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

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1. Introduction

Confidentiality Disclosure Agreements (CDAs) (sometimes called non-disclosure agreements or NDAs) are legal agreements that are often used during the early set-up of commercial contract research in NHS organisations[1]. They facilitate the sharing of confidential information from the commercial company to prospective participating NHS organisations prior to execution of the relevant site agreement.

However, the variety of CDAs presented to NHS organisations by commercial companies is an onerous burden that can be difficult to manage and ensure that the rights and obligations of all parties are covered. There is concern that lengthy negotiations are negatively impacting on the efficiency of study set-up in some cases.

To address the above, a UK-wide partnership has produced these model CDA templates – the model CDA (mCDA) and the model Master CDA (mMCDA). These templates help make the early sharing of information for feasibility and site set-up purposes quicker, clearer, and more consistent, which is in line with the UK Vision for Clinical Research Delivery[2]. The streamlining of this information sharing also helps align NHS and industry with a goal from Lord O'Shaughnessy's independent review to make approving and setting up of clinical trials faster thus making the UK an attractive place in which to carry out these studies[3].

These model CDAs have been developed to ensure that the rights and obligations of all parties are appropriate and that they can be consistently met by the prospective NHS organisation.

2. Use of the CDA templates

These CDA templates should be used for sharing of confidential information by a commercial company to support early feasibility discussions, site selection and set-up up to the point that a subsequent agreement (for example the mCTA) is executed. The CDAs can also be used to share confidential information with NHS organisations which might provide chief investigator services. Both CDAs cover confidential information that has been shared with the NHS organisation even if participation in the study or provision of chief investigator services does not progress. 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. The templates are intended to be used unmodified and proposals to modify them are likely to result in lengthy delay while additional review and negotiations take place.

The CDA templates are one-way and only facilitate the sharing of confidential information from the sponsor to potential participating NHS organisation. They do not facilitate the sharing of confidential information from the NHS organisation to the

[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
[3] Lord O'Shaughnessy review

sponsor or contract research organisation (CRO). Information regarding NHS organisations' capacity and capability is not considered to be confidential. It is expected that information shared regarding NHS staff personal details, such as CVs, require the individual to consent to their data being shared in this way; their employing organisation cannot confirm on their behalf that their personal data can be shared.

These templates do not cover non-commercial research or 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.

Model CDA (mCDA)

The mCDA is a single study model template that requires only project-specific modifications to be made (that is, where indicated in yellow highlight) so basic study-specific identifiers are provided to the NHS organisations. If left otherwise unamended, it is simple, straightforward and swift to execute.

In the mCDA template, Company is used to mean either the Sponsor or its appointed contract research organisation (CRO) which is party to the agreement. The mCDA allows sharing of confidential information for the term selected, with obligations of confidentiality surviving for ten years.

Model Master CDA (mMCDA)

The mMCDA facilitates the disclosure of multiple potential study opportunities between the Company and the NHS organisation. It is based on the mCDA and alleviates the need to seek enactment of specific mCDAs for each individual study / project. However, each disclosure must be accompanied by basic study-specific identifiers which will be sent first to the NHS organisation (in accordance with Schedule 1, outlined in more detail below). The mMCDA will be enacted between a Company (meaning the commercial organisation acting as Sponsor of a study) and the Recipient, although the Company may identify a CRO that they will be working with during the notification process. Again, only Company specific modifications (highlighted in yellow) should be made. Schedule 1 should be included in the agreement when it is executed but as a blank template; it should not be used until after the agreement has been executed. Disclosures can be made at any time from the date of execution, with obligations of confidentiality lasting a further 10 years from date of notification of the potential study. Either party may terminate the mMCDA upon written notice to the other party.

Completion of Schedule 1 – Confidentiality Notification Letter

Whilst this is a master confidentiality agreement which, once enacted, will allow multiple disclosures in an efficient and consistent process, it requires notification to the Recipient each time a new study is added, as set out in Schedule 1. This should be before sharing study specific information and it is important to note that any information shared by the Company to the Recipient will only be deemed Confidential Information where the Recipient Research Support Department has acknowledged receipt. In the template, Research Support Department is used to define the department leading research set-up

within the Recipient's NHS organisation, for example research and development office or research and innovations office.

It is not acceptable to the NHS to use master agreements that do not require the disclosing party to propose 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.

Therefore, before each disclosure, the Confidentiality Notification Letter included in Schedule 1 of the agreement is completed. This letter is emailed to the Recipient's relevant Research Support Department, including any potential proposed investigators, prior to the sharing of study specific confidential information. One Confidentiality Notification Letter should be completed per study or study within a programme.

Completing Schedule 1 will provide the NHS with the following study details:

- Company name;
- the study title and protocol number;
- if the study is part of a programme, the programme title and programme number;
- whether any investigators have been identified, and if not whether the Company requests assistance from the Research Support Department in doing so;
- optional: details of any proposed investigators and email addresses;
- optional: inclusion of CRO's details to identify if the Company is authorising a CRO to disclose confidential information on their behalf for a particular study.

The Company needs to receive a confirmation of receipt or automatic response from the Recipient before sharing their Confidential Information as this is the only way it will be deemed confidential. An example response could be;

> "Thank you for sending the notification advising of the study details which will be forwarded for discussion under the previously agreed model Master CDA (mMCDA).
>
> The disclosed information is covered by obligations of confidentiality for 10 years from the date of this notification. In line with the information set out in the mMCDA, we expect that Confidential Information regarding this project may be shared with us for a maximum of 2 years from the date of this notification.
>
> If you have not already done so, please ensure this notification is also shared with the proposed investigator if known.
>
> We look forward to receiving the study details and shall be in contact about the feasibility of participating in the project."

A list of contact addresses for research support functions within each NHS organisation is provided at the NHS R&D Forum website. These research support functions can

advise on the generic email address their organisation will be using to receive notifications, as will be added to Clause 2.2 in the agreement.

It is the Company's responsibility to:

- provide the fully completed Schedule 1 Confidentiality Notification Letter to the Recipient;
- wait for confirmation of receipt from the Recipient prior to sharing any Confidential Information with them.

It is the Recipient's responsibility to:

- have a generic email address that is monitored during working days to receive notifications;
- inform the Company of receipt of the Confidentiality Notification Letter;
- retain and log the notifications received;
- (optional) have a process in place to ensure Confidential Information is forwarded to the relevant investigators within the organisation if that is preferred locally, or upon agreement with the Company.

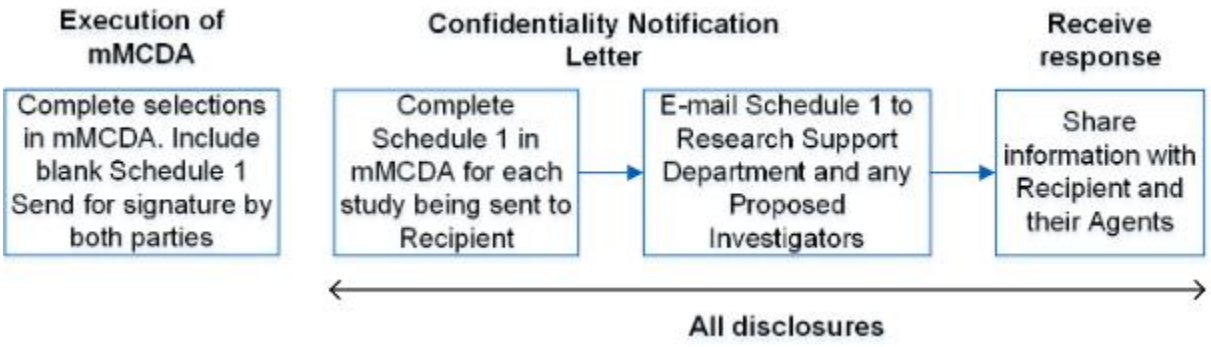

Figure 1: Flow chart illustrating process of using the mMCDA.

Setting up automatic responses to a mMCDA Confidentiality Notification Letter

NHS organisations should ensure that any automatic responses sent from their generic inboxes to confirm receipt of Confidentiality Notification Letters are generated every time an email is received from a Sponsor. The default setting on older versions of Outlook is often to send a single automatic reply, instead of sending an automatic reply every time an email is received. Rules can be used to ensure that an automatic reply is sent every time an email is received. NHS organisations' IT departments may need to set up an appropriate rule on older versions of Outlook using administrator access.

The Microsoft Support website has guidance about when and how to set up rules for automatic replies.

3. Authorised signatories

Companies are reminded to ensure that the agreement is sent for Recipient's authorised signature, usually through their lead research support department, and not proposed investigators of the study. Additionally, investigators should not be asked to sign CDAs through online document-sharing portals. 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 3.3 in the templates;

> *"3.3 to disclose Confidential Information only to such Agents of the Recipient who have a specific need to receive such Confidential Information for the Purpose, and who are bound by obligations of confidentiality towards Recipient that are substantially similar to those under this Agreement. The Recipient remains responsible for the compliance of its Agents."*

4. 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)[4], The Records Management Code of Practice for Health and Social Care (2021)[5], NHS Information Governance - Guidance on Legal and Professional Obligations (2007)[6], The Information Security Management: NHS Code of Practice (2007)[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.

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

- **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. Contacts for queries and feedback

The mCDAs are reviewed every 6 months based on feedback received. To send feedback or ask a question about the templates please contact the Four Nations Contract Leads as follows:

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

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

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

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

All queries may be subsequently passed onto the NHS R&D Forum Contracts Working Group at info@rdforum.org.uk

6. Change history

Summary of key changes in July 2025

Recitals

Clarification of the recitals in mCDA to be clearer for use depending on whether the Company is the Sponsor or the CRO.

Addition of an optional recital to the mCDA to clarify where the Sponsor is the Company

Definitions

Updated definition of Agent to clarify that this includes chief investigators contracted through a model commercial chief investigator agreement (mCCIA), enabling clauses within the mCDAs and mCCIAs to work together and allow the sharing of Confidential Information.

Updated definition of Confidential Information to clarify that this includes sharing information provided by the Sponsor's Agents, enabling clauses within the mCDAs and mCCIAs to work together and allow the sharing of Confidential Information.

Clarify that the Research Support Department is within the Recipient organisation, referring to the defined term in the Agreement.

Clauses

Clarified within Clause 3.3 that the Recipient will enforce obligations of confidentiality on its Agents at the Company's request.

Clarification in Clause 10 of mMCDA that Confidential Information regarding a study can be exchanged for 2 years after the Recipient confirms receipt of the related Confidentiality Notification Letter.

Appendix 1

Addition of this Appendix to be used where an Affiliate or other third party has been delegated authority to enter into the Agreement on behalf of the Sponsor.

Schedule 1

Clarification made regarding use of the Confidential Notification Letter.

Clarification made to the notification of proposed investigators.

Summary of key changes in April 2024

General

New model master agreement (mMCDA) published to enable commercial organisations to contract once with NHS / HSC organisations and add different studies under the confidentiality agreement.

Alignment of mCDA to changes brought in with mMCDA.

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.