# MODEL MASTER CONFIDENTIALITY DISCLOSURE AGREEMENT (mMCDA)

**Between**

● [**INSERT** NAME OF COMPANY AND REGISTERED ADDRESS OF COMPANY]

**“The Company”**

and

● [**INSERT** NAME OF RECIPIENT ORGANISATION and ADDRESS OF RECIPIENT ORGANISATION]

**“The Recipient”**

Each of which shall be a **“Party”** and collectively the **“Parties”**.

**Whereas**:

1. [**Insert** full Company name] a company registered in [**insert** Country] with company number [**insert** Registered Company Number], whose registered office is [**insert** address] (also known as the “Sponsor”) is willing to disclose certain Confidential Information (as hereinafter defined) to the Recipient for the purpose of discussions relating to clinical trial programmes or studies under development by Company and / or its Affiliates (hereafter defined); (the “Purpose”).
2. The Company wishes to protect such Confidential Information and accordingly the Parties have agreed to the terms and conditions of protection contained in this Agreement (the “Agreement”).

NOW THEREFORE THE PARTIES HAVE AGREED AND DO HEREBY AGREE AS FOLLOWS:

1. In this Agreement:
	1. **Affiliate** means any business entity that controls, is controlled by or is under the common control with the Company, save where there are contractual arrangements in place to exclude such affiliate. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity, by contract or otherwise.
	2. **Agent** shall include but is not limited to, (1) any person (including any proposed investigator, nurse or other healthcare professional) providing services to the Recipient under a contract for services (commonly known as an honorary contract) or otherwise any such person’s principal employer in the event that it is not the Recipient and / or (2) any contracted third party providing services to a Party under a contract for services or otherwise (including but not limited to a chief investigator engaged under a model Commercial Chief Investigator Agreement between the Sponsor and an NHS or HSC chief investigator employer).
	3. **Confidential Information** means in each case in connection with the Purpose all information provided by, or made available by, the Company, an Affiliate or an Agent of the Company or obtained as a result of this Agreement, including but not limited to, information on current or proposed research projects, results, data, conclusions, draft or proposed protocols, feasibility questionnaires and / or information on clinical research and development, procedures, technologies, strategy, science, finance, business, know-how and intellectual property of the Company, and / or its Agents or Affiliates, whether disclosed orally, electronically or in any other way whatsoever of representing or recording information.
	4. **Confidentiality Notification Letter** means the completed Confidentiality Notification Letter contained in Schedule 1 which is emailed to the Research Support Department by the Company prior to the disclosure of Confidential Information relating to a new clinical trial programme or study.
	5. **CRO** means the Contract Research Organisation that can disclose the Company’s Confidential Information if declared under Schedule 1 of the Agreement.
	6. **EIR** means either the Environmental Information Regulations 2004 or the Environmental Information (Scotland) Regulations 2004, as applicable to the place of constitution of the Recipient.
	7. **FOIA** means either the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002, as applicable to the place of constitution of the Recipient.
	8. **Research Support Department** means the department leading research set-up within the Recipient, for example; research and development office, research and innovation office.
2. **Purpose**
	1. In order to enable the Parties to engage in discussions for the Purpose, the Company may disclose Confidential Information to the Recipient subject to the terms and conditions of this Agreement. The Company may disclose to the Recipient such Confidential Information within its possession or control, as it deems necessary and appropriate, for the Purpose. The Recipient shall accept and hold such Confidential Information in strict confidence in accordance with the provisions of Clause 3 below.
	2. The Company may add individual clinical trial programmes or studies to this Agreement by notifying the Recipient Research Support Department at [insert generic Recipient email address] of their intention to do so in line with Schedule 1. Individual clinical trial programmes or studies shall only be incorporated within this Agreement where the Research Support Department has provided written confirmation of receipt of the email notification from the Company.
	3. Any information shared by the Company to the Recipient shall only be deemed Confidential Information where the Recipient has been notified of Company’s intention to share the information and the Recipient has confirmed receipt of such notification in accordance with Clause 2.2 of this Agreement. This requirement shall apply in relation to each opportunity the Parties seek to collaborate.
	4. Confidential Information must be provided separately for each clinical trial programme OR study under consideration.
3. The Recipient undertakes for so long as the Confidential Information remains confidential in character:
	1. to keep all Confidential Information confidential and to take reasonable endeavours, consistent with the steps it takes to protect its own comparable confidential information, to ensure that copies including the original received of the Confidential Information made by or on behalf of the Recipient are protected against theft or other unauthorised access;
	2. not to communicate or otherwise make available any such Confidential Information to any third party except with specific prior written consent from the Company, save where disclosure is required by a regulatory authority or by law (including any disclosure required to ensure compliance, by the Recipient, with the applicable FOIA and / or EIR in accordance with Clause 5 of this Agreement). The Recipient shall inform the Company, within a reasonable time prior to being required to make the disclosure (and, where appropriate, in accordance with Clause 5), of the requirement to disclose and the information required to be disclosed and the Recipient shall disclose the minimum amount of Confidential Information which are strictly required to abide with the compulsory disclosure;
	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 (which obligations the Recipient agrees to enforce at the request of the Company). The Recipient remains responsible for the compliance of its Agents; and
	4. not to use, or allow to be used, Confidential Information other than solely for or in relation to the Purpose, unless (and then only to the extent to which) any other use shall have been specifically authorised in writing by the Company.
4. The obligations in Clause 3 shall not apply, or shall cease to apply, to such Confidential Information as the Recipient can show to the reasonable satisfaction of the Company:
	1. has become public knowledge other than through any fault of the Recipient;
	2. which Recipient can show by written record was already known to the Recipient prior to disclosure by the Company and without any obligation of confidence;
	3. which Recipient can show by written record was independently developed by the Recipient without recourse to or use of any Confidential Information;
	4. has been received by the Recipient from a third party who, as far as the Recipient is aware, did not acquire it in confidence from the Company or any Affiliate, or someone owing a duly known duty of confidence to the Company or any Affiliate.
5. The Company acknowledges that the Recipient is subject to the applicable EIR and FOIA. This includes associated guidance and codes of practice.
	1. If the Recipient or its Agent(s) receive a request under the FOIA and / or EIR to disclose information relating to this Agreement, or the Purpose, it will notify the Company as soon as is reasonably practicable, and in any event, no later than five (5) working days after receiving the request. The Recipient will consult with the Company in accordance with all applicable guidance.
	2. The Company acknowledges that subject to Clause 5.2.1, the decision on whether any exemption applies to a request for disclosure of recorded information under the FOIA and / or EIR is a decision solely for the Recipient.
		1. The Company shall cooperate with the Recipient and shall use its reasonable endeavours to respond within ten (10) working days of the Recipient’s reasonable request for assistance.
	3. Where the Recipient determines that it will disclose Confidential Information pursuant to FOIA and / or EIRs, notwithstanding any objections from the Company, it will notify the Company in writing, giving at least four (4) working days’ notice of its intended disclosure.
6. The Recipient may make only such copies of Confidential Information as are strictly necessary for the Purpose and must ensure that all such copies are clearly marked as confidential and can be clearly separated from the Recipient’s own information. Any copy so made shall also constitute Confidential Information. The Recipient shall, upon the Company’s written request and at the expense of the Company, return to the Company all Confidential Information as is in tangible form (together with all copies thereof within its possession or control) or make such other disposal thereof as may be stipulated by the Company. Notwithstanding the foregoing, the Recipient may retain one (1) copy of the Confidential Information for audit purposes. The Recipient shall not be required to destroy any electronic back-up that has been created solely by its automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with its standard archiving and document retention policies. Any Confidential Information retained in accordance with the foregoing exceptions shall continue to be protected by the Recipient in accordance with the provisions of this Agreement.
7. Except as expressly provided, nothing in this Agreement nor the subsequent disclosure of Confidential Information pursuant to this Agreement shall be construed as any partnership or joint venture between the Parties and the signing of this Agreement shall not be construed as a commitment or obligation, whether express or implied, on the part of either Party to conduct further negotiations or to enter into any further agreement with the other.
8. The rights and obligations of the Parties under this Agreement are personal and may not be assigned or otherwise transferred at any time without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that Company may have the option of assigning rights (though not obligations) to one or more of its Affiliates; provided that it shall be a requirement in all cases of assignation that the assignee undertakes to perform all outstanding obligations of the assignor as though the assignee had been an original Party hereto.
9. This Agreement is intended by the Parties hereto as the final expression of their understanding with respect to the subject matter hereof and is the complete and exclusive statement of the terms hereof notwithstanding any oral representations or statements to the contrary heretofore made.
10. This Agreement shall commence on the last date of execution hereof. The ability to exchange Confidential Information under a duly executed Confidentiality Notification Letter shall terminate 2 years after the date the Recipient confirms receipt of such applicable Confidentiality Notification Letter. Recipient’s obligations of Confidentiality shall survive for a period of ten (10) years from confirmation of receipt of notification of each potential study as detailed on receipt of the completed Confidentiality Notification Letter contained in Schedule 1. The obligations of confidentiality in this Agreement shall apply to all Confidential Information disclosed by the Company or any Affiliate for the Purpose, whether disclosed on or after the date of execution of this Agreement.
11. In the event that the Parties elect to enter into a subsequent clinical trial programme or study agreement in relation to a clinical trial programme or study under this Agreement, the obligations of confidentiality under this Agreement shall terminate for that clinical trial programme or study. Rights and obligations in relation to the Confidential Information shall be as specified in the separate clinical trial programme or study agreement.
12. Either Party may terminate this Agreement upon written notice to the other Party; provided, however, the termination of this Agreement shall not affect any rights or obligations which have accrued prior thereto nor shall it affect then-existing Confidentiality Notification Letters, which shall continue until otherwise terminated in accordance with the provisions at Clause 10 herein as if this Agreement had not otherwise expired or terminated.
13. The terms of this Agreement may only be amended or modified by written agreement signed by the authorised representatives of the Parties.
14. The Recipient’s use of any Confidential Information provided to it pursuant to this Agreement shall be conducted at the Recipient’s own risk and the Company shall have no liability with respect thereto.
15. Where the Recipient is constituted in England, Wales or Northern Ireland, in the event of breach of this Agreement, money damages may be inadequate to remedy any such breach. As a result, the Company may seek, and a court of competent jurisdiction may be requested to grant, an order for performance, or injunctive relief or any other relief as a remedy for any breach of this Agreement. Such remedy may be in addition to all other remedies, including money damages, available to the Company at law or at equity.

Where the Recipient is constituted in Scotland, in the event of breach of this Agreement, money damages may be inadequate to remedy any such breach. As a result, the Company may seek, and a court of competent jurisdiction may be requested to grant, an order for specific implement, an interdict or interim interdict or any other relief as a remedy for any breach of this Agreement. Such remedy may be in addition to all other remedies, including money damages, available to the Company at law.

1. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument and may be exchanged via electronic mail in portable document format (“pdf”) or using electronic signatures.
2. Nothing in this Agreement is intended to confer on any person any right to enforce any term of this Agreement which that person would not have had but for the Contracts (Rights of Third Parties) Act 1999 or Contracts (Third Party Rights) (Scotland) Act 2017.
3. The furnishing of Confidential Information to the Recipient shall not constitute any grant, option or license to same under any patent or other rights now or hereinafter held by Company or held by any third party from whom Company receives information protected by a confidentiality agreement and Company reserves all rights and privileges therein, excluding as outlined in this Agreement.
4. If any clause or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision shall, to the extent required, be severed from this Agreement and shall be ineffective without, as far as possible, modifying any other clause or part of this Agreement and shall not affect any other provisions of this Agreement which shall remain in full force and effect.
5. Where the Recipient is constituted in England then this Agreement shall be governed and construed in accordance with the laws of England and Wales and the Courts of England and Wales shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the Recipient is constituted in Wales then this Agreement shall be governed and construed in accordance with the laws of England and Wales as applied in Wales and the Courts of England and Wales shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the Recipient is constituted in Scotland, this Agreement shall be governed and construed in accordance with the laws of Scotland and the Courts of Scotland shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the Recipient is constituted in Northern Ireland, then this Agreement shall be governed and construed in accordance with the laws of Northern Ireland and the Courts of Northern Ireland shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

IN WITNESS WHEREOF this Agreement is executed as follows:

|  |  |
| --- | --- |
| Signed for and on behalf of [**INSERT** name of Company]:OrSigned by [INSERT name of organisation] for and on behalf of [INSERT NAME OF SPONSOR], as duly authorised under Appendix 1Signature:Print name:Title:Date: | Signed for and on behalf of [**INSERT** name of Recipient]:Signature:Print name:Title:Date: |

*N.B. It is a requirement in Scotland, and best practice throughout the UK, that the signature pages of the Agreement are part of the body of the Agreement. Please therefore ensure that the last clause of the Agreement appears on the same page as the signature block.*

# Appendix 1 – Formal Delegation of Authority to a Corporate Affiliate or Other Party to Contractually Bind Sponsor

[ ]  If this box is checked, this Appendix 1 (Formal Delegation of Authority to a Corporate Affiliate or Other Party to Contractually Bind Sponsor) is not used.

### Schedule 1: Notification Process after execution of the mMCDA

1. From Schedule 1, Confidentiality Notification Letter is completed by Company

2. Email the Confidentiality Notification Letter to Recipient’s Research Support Department and if identified, the Proposed Investigator(s).

3. The Company will receive confirmation of receipt or other automatic response. The obligations of confidentiality will not apply to a clinical trial programme or study until confirmation of receipt is received.

4. Company (or named CRO if applicable) can share Confidential Information immediately following confirmation of receipt with the Recipient’s Agents.



**Confidentiality Notification Letter**

Recipient: [Insert Name of NHS/HSC Recipient]

Recipient Address: [Insert postal Address of Recipient]

Email: [insert **generic email address** for Research Support Department]

Cc Email: [insert Proposed Investigator’s email address] (if Proposed Investigator known)

Date [DD/MM/YYYY]

To whom it may concern

**Regarding Study Title:** [insert full study title]

**Protocol Number (or other reference):** [insert protocol number or reference as applicable]

**[(Option if this letter is regarding a programme of studies) Regarding Programme Title:** [insert full programme title]]

[**(Option is this letter is regarding a programme of studies) Programme Number (or other reference):** insert programme number or reference as applicable]]

**Company:** [insert name]

[**(Option 1)**: The Company has not yet identified any potential Investigators. The Company would like the Research Support Department's help to identify potential Investigators.]

[**(Option 2)**: The Company has identified potential Investigators.

**Proposed Investigator/s:** [if known insert name/s]

**Email of Proposed Investigator/s:** [insert email address/es]]

Further to the model Master Confidentiality Agreement mMCDA (“Agreement”) between [insert NHS Organisation] (“Recipient”) and [insert Company name] (“Company”) effective as of [insert date], the Company shall be disclosing Confidential Information relating to the above-mentioned study to the Recipient and any Proposed Investigator identified above. This notification allows the Company to share information with the Agents of the Recipient as required for the purpose, with disclosures bound by terms of Clause 3.3 of the mMCDA;

“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;”

Such Confidential Information disclosed shall be subject to the terms and conditions of the Agreement as from the date we receive confirmation of receipt of this notice from you for a period of ten (10) years in accordance with the terms of the Agreement. If a subsequent clinical trial programme or study is enacted for your organisation to participate in this study then these obligations of confidentiality will be superseded by that agreement.

[(**Include if Company is using a CRO, delete if not applicable**) The Company confirms the CRO [**insert** CRO name] registered in [**insert** Country] with company number [**insert** Registered Company Number], whose registered office is [**insert** address] will be sharing Confidential Information on its behalf in relation to the study title provided above. (**Duplicate if more than one CRO being used**).]

Yours sincerely,

[Insert name and position]

[Company name and address]

[Delete if not applicable CC–Recipient Proposed Investigator/s (if known)]