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Master Indemnity Agreement

Guidance

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Part A
MIA Call-Off Agreements

1. The MIA Call-Off Agreement is an agreement entered into directly by an NHS Trust or another NHS organisation (“Authority”) with a supplier (“Supplier”) when it is in receipt of equipment (to include products) (“Equipment”) from a Supplier, on either a loan or transfer basis, for purposes to be set out as part of such MIA Call-Off Agreement. The current version of the template MIA Call-Off Agreement can be found at https://www.gov.uk/government/publications/master-indemnity-agreement-mia and should be completed by the Authority and Supplier each time a piece of Equipment is provided under these arrangements. A failure to complete such an MIA Call-Off Agreement in relation to a piece of Equipment will mean that the parties will not get the protections afforded by these arrangements. For example, the Authority will not get the benefits of the relevant indemnity provisions and the Supplier will not get the benefit of the legally binding commitments given by the Authority as referred to at paragraph 4 below and the contractual limitations of liability, as set out in the Master Indemnity Agreement Terms and Conditions (see below). For the avoidance of doubt, these arrangements are not suitable for clinical investigations where the equipment is the subject of the investigation. The insurance and indemnity arrangements for clinical investigations should be agreed through use of the model Clinical Investigation Agreement (mCIA).

2. Where equipment is loaned or gifted specifically for use in clinical research, where that equipment is not the subject of the research, the MIA may be appropriate. Alternatively, the insurance and indemnity arrangements may be agreed through the site agreement. Under Health Research Authority (“HRA”) Approval, such agreements and associated insurance and indemnity arrangements are assessed centrally by the HRA For further guidance on HRA Approval and other projects, please see: http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/. For model agreements relating to various research scenarios please see http://www.ukcrc.org/regulation-governance/model-agreements/.

3. Where a supplier has entered into an Overarching Master Indemnity Agreement with the Department of Health (see Part B below), this means that the Department of Health has checked the Supplier’s insurance arrangements and so they do not need to be checked again by the Authority at the point that Supplier enters into an MIA Call-Off Agreement. The standard practice is for all Suppliers to enter into an Overarching Master Indemnity Agreement with the Department of Health before entering into any specific MIA Call-Off Agreements (which can be with any NHS Trust or other NHS body in England). The Authority should routinely check the Master Indemnity Agreement Register when a Supplier completes an MIA Call-Off Agreement to confirm the Supplier’s Overarching Master Indemnity Agreement registration is still valid and its insurance is showing as current. If a Supplier is party to an Overarching Master Indemnity Agreement, this will be noted as part of the Master Indemnity Agreement Register published at: https://www.gov.uk/government/publications/master-indemnity-agreement-mia.

4. In exceptional circumstances (i.e. for reasons of urgency where it is not possible for the Supplier to enter into an Overarching Master Indemnity Agreement with the Department of Health prior to the delivery of the Equipment or the Master Indemnity Agreement Register is not showing that the Supplier has current insurance), an Authority can still enter into an MIA Call-Off Agreement with a Supplier, but should only do this once it has carried out the necessary insurance checks itself. In these circumstances the Supplier’s details / updated details will not be entered onto the Department of Health’s Master Indemnity Agreement Register until such time as an Overarching Master Indemnity Agreement has been entered into by the Supplier with the Department of Health and/or, where an Overarching Master Indemnity Agreement is in place but the insurance is not showing as current, the updated insurance details have separately been provided to the Department of Health by the Supplier.
5. The MIA Call-Off Agreement incorporates the Master Indemnity Agreement Terms and Conditions published by the Department of Health, which can be found at https://www.gov.uk/government/publications/master-indemnity-agreement-mia. The Authority has various rights and obligations under the Master Indemnity Agreement Terms and Conditions and should, therefore, review these terms and conditions prior to entering into any MIA Call-Off Agreement to confirm that they are appropriate for what is intended in terms of the relevant loan or transfer of Equipment. As part of this review, the Authority should confirm that it can comply with its obligations under the Master Indemnity Agreement Terms and Conditions. For example, the Authority’s obligations to provide reasonable cooperation to the Supplier and to pay for any damage to Equipment to the extent it is caused by:

(i) the Authority failing to use or operate such Equipment in accordance with the express written instructions of the Supplier;

(ii) a negligent act or omission of the Authority; or

(iii) any modifications made to the Equipment not expressly authorised by the Supplier. As part of its review, the Authority should also confirm that the liability provisions (including, without limitation, any limitations on the liability of either party) set out as part of the Master Indemnity Agreement Terms and Conditions are appropriate.

6. Since the mutual exchange of obligations and promises is regarded as consideration, the MIA Call-Off Agreement, forms a legally binding contract.

7. A flowchart illustrating the process for entering into MIA Call-Off Agreements is attached at Annex A to this Guidance.

8. A flowchart illustrating the process for clinical investigations is attached at Annex B to this Guidance.
Part B
Overarching Master Indemnity Agreement Guidance for Suppliers

1. The current template for the Overarching Master Indemnity Agreement to be entered into by the Department of Health and a Supplier can be found at https://www.gov.uk/government/publications/master-indemnity-agreement-mia. Where a Supplier enters into an Overarching Master Indemnity Agreement with the Department of Health, it undertakes that:

   a. It will comply with the then current version of Master Indemnity Agreement Terms and Conditions as published by the Department for Health from time to time on the gov.uk website when providing any Equipment to the National Health Service and that such terms and conditions will form part of any MIA Call-Off Agreement with the relevant Authority to which any Equipment is supplied (to include on both a loan and transfer basis).

   b. Any public liability and product liability insurance information together with any other information provided to the Department of Health is accurate and will be kept up-to-date to ensure that the Department of Health always has copies of the Supplier’s current insurance policy details (to include confirmation of all renewals and policy changes) and company details (to include prompt notification of any name changes) accompanied with relevant supporting documentation.

   c. It will not supply any Equipment to an Authority pursuant to an MIA Call-Off Agreement unless that Equipment is covered by appropriate insurance arrangements in accordance with the insurance requirements set out in the applicable Master Indemnity Agreement Terms and Conditions.

   d. The Department of Health may make publically available (to include, without limitation, by sharing with other NHS organisations and other relevant public sector organisations within the United Kingdom and by publishing information on the gov.uk website) this Overarching Master Indemnity Agreement and any information provided to the Department of Health by the Supplier under and/or in connection with this Overarching Master Indemnity Agreement.

   e. It is a properly constituted entity fully empowered by the terms of its constitutional documents to enter into this Overarching Master Indemnity Agreement and has obtained any required consents or approvals.

2. The benefits for a Supplier in entering into an Overarching Master Indemnity Agreement with the Department of Health include:

   a. The Supplier’s details are entered as part of the Master Indemnity Agreement Register published at: https://www.gov.uk/government/publications/master-indemnity-agreement-mia.

   b. The Supplier will be given an Overarching Master Indemnity Agreement number, which will mean that an Authority (which could be any NHS Trust or other NHS body in England) will not be required to check the Supplier’s insurance for compliance with the Master Indemnity Agreement Terms and Conditions provided that the Master Indemnity Agreement Register is showing that such insurance (as checked by the Department of Health) is current.
3. The instructions for Suppliers that wish to enter into an Overarching Master Indemnity Agreement are as follows:

a. Enter the company's details on the first page of the template Overarching Master Indemnity Agreement, leave the space for the Overarching Master Indemnity Agreement number blank.

b. An authorised signature from the Supplier’s organisation is required at the bottom of the Overarching Master Indemnity Agreement along with details of the person signing and the date of signature.

c. The signed Overarching Master Indemnity Agreement should then be e-mailed to the Department of Health at the e-mail address set out in Part C below. Scanned proof of insurances for the Supplier for both public and product liability must accompany the signed Overarching Master Indemnity Agreement and this must demonstrate compliance with the insurance requirements set out at Clause 6.1 of the Master Indemnity Agreement Terms and Conditions. This proof of insurances must include copies of the relevant insurance documents and a covering note referring to the relevant provisions that demonstrate such compliance. As a minimum, this covering note should refer to the relevant provisions in the insurance policy documents demonstrating: (i) the amount of cover per claim for both public liability and product liability; (ii) the period of cover; and (iii) who is protected by the insurance policy (which should be consistent with the name of the party seeking to enter into the Overarching Master Indemnity Agreement). A failure by a Supplier to provide a clear covering note for these purposes will result in the documents being sent back to the Supplier to correct this omission prior to the Department of Health executing the Overarching Master Indemnity Agreement.

d. Once the agreement has been checked by the Department of Health, the Master Indemnity Agreement number is inserted and then signed by Department of Health, a scanned copy of the signed agreement will then be sent to the Supplier at the contact email address provided by the Supplier for its records. For the avoidance of doubt, an Overarching Master Indemnity Agreement will not come into effect until it is signed by the Department of Health.

e. Appropriate details will then be included by the Department of Health in the Master Indemnity Agreement Register, as referred to above.

f. As the Master Indemnity Agreement Register is updated on a regular basis, Suppliers and Authorities can check with the Department of Health (using the contact details at Part C below) for confirmation of registrations if there is doubt about a particular Supplier’s status in terms of having a current Overarching Master Indemnity Agreement and/or current insurance policy in place.

4. The instructions for Suppliers that wish to maintain an Overarching Master Indemnity Agreement are as follows:

a. Every time an insurance policy is about to expire, the Supplier must ensure he submits a copy of the appropriate renewal certificate via email to the Department of Health using the contact details at Part C below. No new Overarching Master Indemnity Agreement needs to be signed at the expiry of the insurance policy if the Supplier provides renewal certificate. The renewal certificate must demonstrate compliance with the insurance requirements set out at Clause 6.1 of the Master Indemnity Agreement Terms and Conditions and should be accompanied by a covering note: (i) referring to the relevant provisions that demonstrate such compliance; and (ii) highlighting (a) any policy changes not already notified to the Department of Health; or confirming (b) that there have not been any policy changes that have not already previously been notified to the Department of Health. A failure by a Supplier to provide such a renewal certificate and/or a clear covering note for these purposes may result in the Department of
Health terminating the Supplier’s Overarching Master Indemnity Agreement and removing its
details from the Master Indemnity Agreement Register.

b. Following receipt and checking of the information referred to at point 4a above and assuming
everything is in order, the Master Indemnity Agreement Register will be updated to show the
new insurance policy expiry date. Confirmation of the update will be sent by the Department
of Health to the Supplier as all details can be checked on the Master Indemnity Agreement
Register.
Part C
Enquiries and contact details

1. If in doubt about any aspect of the templates or any other parts of this guidance you should contact the Department of Health via email at: mia@dh.gsi.gov.uk in the first instance.

2. Completed Overarching Master Indemnity Agreements, any scanned documents relating to the insurance checks carried out by the Department of Health in connection with such Overarching Master Indemnity Agreements, any notifications relating to any undertakings provided by the Supplier under any Overarching Master Indemnity Agreement, and any information required by the Department of Health in relation to any MIA Call-Off Agreement should be sent by e-mail to: mia@dh.gsi.gov.uk
Flowchart for health research

Supplier contacts Trust to provide equipment free

Is the equipment being provided as part of a health research project?

No

See Annex A MIA process

Yes

Is the equipment the subject of a clinical investigation?

Yes

Advise supplier to use model clinical investigation agreement mCIA

No

Refer to the HRA initial Assessment/Approval letter for guidance on whether the sponsor intends to provide indemnity for the equipment via the site agreement or separately via MIA


Link to model clinical investigation agreements  – http://www.ukcrc.org/regulation-governance/model-agreements/