



Master Indemnity Agreement

Guidance notes for the 2018 update

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Contents

Part A – MIA Call-Off agreements	1
Part B - General Guidance for NHS	3
Scope	3
Copy of MIA Call-off Agreements	3
Delivery of Equipment	4
Data Security and Protection Toolkit	4
Network and Information Systems	5
OES Supply Chains	5
Summary of OES and DSP Toolkit	5
Data Protection Protocol	6
Part C - Overarching MIA Guidance for Suppliers	7
Part D - Enquiries and Contact details	10

Part A – MIA Call-Off agreements

- 1.1 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, without financial payment, for purposes to be set out as part of such MIA Call-Off Agreement. The current updated version of the template MIA Call-Off Agreement can be found at the [MIA website](#) 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 in relation to that Equipment. 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 in paragraph 1.3 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 trials, clinical investigations or other research projects. Research projects in the NHS in England are expected to have appropriate agreements in place that would cover insurance and indemnity arrangements for any loaned and/or gifted equipment. 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 consult the [HRA website](#). For model agreements relating to various research scenarios please consult the [UKCRC website](#).
- 1.2 Where a supplier has entered into an Overarching Master Indemnity Agreement with the Department of Health and Social Care (see Part B below), this means that the Department of Health and Social Care 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 and Social Care 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 published [Master Indemnity Agreement Register](#).

- 1.3 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 and Social Care 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 and Social Care'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 Social Care 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 and Social Care by the Supplier.
- 1.4 The MIA Call-Off Agreement incorporates the Master Indemnity Agreement Terms and Conditions published [online](#) by the Department of Health and Social Care. 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:
- the Authority failing to use or operate such Equipment in accordance with the express written instructions of the Supplier;
 - a negligent act or omission of the Authority; or
 - 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.
- 1.5 Since the mutual exchange of obligations and promises is regarded as consideration, the MIA Call-Off Agreement, forms a legally binding contract.
- 1.6 A flowchart illustrating the process for entering into MIA Call-Off Agreements is attached at Annex A to this Guidance.

Part B - General Guidance for NHS

Scope

- 1.7 The Master Indemnity Agreement covers the free use of the Equipment (for the purpose of evaluation, testing, research, design, or trial demonstration of equipment) provided on a loan basis or transferred for free and on a no hire and no purchase basis, including Hardware goods which include dedicated bespoke software for Medical purposes.
- 1.8 The Master Indemnity Agreement is not to be used for the acquisition (loan or free issue) of software products, which can be purchased separately for use with the Equipment, as the standard level of indemnity required is not sufficient to cover the cost of damages associated with the potential risks that accompany software products. The only exception to this is for software that is integral to the Equipment and as such is embedded in or forms parts of the Equipment. Otherwise all other software must be sourced separately and is outside the scope of this Master Indemnity Agreement.
- 1.9 The Master Indemnity Agreement must be used in all loan / free of charge arrangements with suppliers to provide the Authority with legal and financial protections.
- 1.10 The Master Indemnity Agreement should also not be used for obtaining any service/maintenance support or other associated services required for the use of the Equipment, all such services are outside the scope of this agreement, as the decisions to obtain such services may have procurement implications and therefore the Authority should ensure that the sourcing of such services is done in compliance with applicable regulations and their own internal governance and decision-making processes.

Copy of MIA Call-off Agreements

- 1.11 The Authority must advise the Supplier whether or not the Data Protection Protocol will apply to the MIA Call Off Agreement by either a “yes” or “no”.
- 1.12 The Authority is responsible for completing sections 19, 20 and 21 of the MIA Call-Off Agreement.
- 1.13 The Authority must send a copy of all MIA Call Off Agreements that the Authority has entered into to the Department of Health and Social Care as soon as possible after the MIA Call Off has been signed by both the Authority and the Supplier. The

MIA Call Offs must be sent to the Department of Health and Social Care at the following address: mia@dhsc.gov.uk

- 1.14 The Authority must ensure that the Supplier has a sufficient period of Indemnity for the duration of the agreed loan period. If the agreed loan period is longer than the current duration of the Suppliers' Indemnity then the Authority must ensure that the supplier renews their Indemnity cover and ensure that the Supplier informs the Department of Health and Social Care by sending the appropriate insurance certificates. The duration of a Suppliers' Indemnity can be referenced on the [Master Indemnity Agreement Register](#).

Delivery of Equipment

- 1.15 The Authority must ensure that if the Supplier has chosen to use a courier service to deliver the goods to the Authority that the Supplier is aware that they must complete and sign the MIA Call Off agreement and include the completed and signed MIA Call Off agreement in the delivery to the Authority. This is to ensure that the supplier agrees to the terms stipulated in the Master Indemnity Agreement [Terms and Conditions](#).
- 1.16 At the end of the loan period the Authority must ensure that it then returns the goods to the Supplier in the manner that is described in the Master Indemnity Agreement Call Off agreement.
- 1.17 The Authority must ensure that in the circumstances where the Supplier is no longer covered by Public and Product liability insurance that they cease all usage of the goods that were previously covered by the Master Indemnity Agreement. The Authority must also inform the Supplier that they are no longer using the goods and return then the goods to the Supplier in the manner that is described in the Master Indemnity Agreement Call Off agreement.

Data Security and Protection Toolkit

- 1.18 From April 2018, the Data Security & Protection Toolkit ("DSP Toolkit") replaces the IG Toolkit. The DSP Toolkit can be accessed [online](#).
- 1.19 The DSP Toolkit is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's 10 data security standards.
- 1.20 All organisations that have access to NHS patient data and systems must use the DSP Toolkit to provide assurance that they are practising good patient data and systems security and that personal information is handled correctly.

Network and Information Systems

- 1.21 From May 2018, the Network and Information Systems Regulations 2018 (the “NIS Regulations”) apply to NHS Trusts, NHS Foundation Trusts and any other person designated by the Secretary of State for Health and Social Care, each is an “operator of essential services” (“OES”) in the health sector for the purposes of the NIS Regulations.
- 1.22 DHSC’s approach is to as far as possible to integrate the implementation of the NIS Regulations [with existing tools and mechanisms]. As such the DSP Toolkit will also be used to ensure compliance with the NIS Regulations.
- 1.23 DHSC has published [guidance](#) on the NIS Regulations which sets the approach DHSC are taking with the implementation of the NIS Regulations.

OES Supply Chains

- 1.24 It should also be noted that the NIS Regulations do not apply directly to the supply chains of an OES. However, as an OES under the NIS Regulations, it has to comply with specific regulatory obligations with regards to the essential services it provides.
- 1.25 In particular it is the responsibility of an OES to put in place appropriate and proportionate measures, and consequently as part of this, to ensure that their suppliers have in place appropriate measures, to manage risks of their services being disrupted via their supply chain.
- 1.26 The OES’s suppliers should understand and manage security risks to [patient data and systems] supporting the delivery of their essential services that arise as a result of dependencies on suppliers. This includes ensuring that appropriate measures are taken when suppliers provide Equipment for essential services or that may impact on essential services of an OES.

Summary of OES and DSP Toolkit

- 1.27 An OES is expected to fulfil the security duties under the NIS Regulations and use the DSP Toolkit. Consequently obligations under the MIA Terms and Conditions have been updated to now include compliance with the DSP Toolkit which is the successor framework to the IG Toolkit. The DSP Toolkit incorporates the requirements for fulfilling data and security duties under the GDPR and the NIS Regulations (including incident reporting).
- 1.28 Updated requirements are now set out in Schedule 1 (Information Governance and System Security Provisions) of the MIA Terms and Conditions.

Data Protection Protocol

- 1.29 If the Supplier confirms in the MIA Call-Off Agreement that there are Data Protection implications, then the [Data Protection Protocol](#) will also need to be completed by the Trust/Supplier to ensure GDPR compliance.

Part C - Overarching MIA Guidance for Suppliers

- 1.30 The current template for the Overarching Master Indemnity Agreement to be entered into by the Department of Health and Social Care and a Supplier can be found on the [mia.gov page](https://www.mia.gov.uk). Where a Supplier enters into an Overarching Master Indemnity Agreement with the Department of Health and Social Care, it undertakes that:
- It will comply with the then current version of Master Indemnity Agreement Terms and Conditions as published by the Department for Health and Social Care 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).
 - Any public liability and product liability insurance information together with any other information provided to the Department of Health and Social Care is accurate and will be kept up-to-date to ensure that the Department of Health and Social Care 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.
 - 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.
 - The Department of Health and Social Care may make publicly 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 and Social Care by the Supplier under and/or in connection with this Overarching Master Indemnity Agreement.
 - 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.

1.31 The benefits for a Supplier in entering into an Overarching Master Indemnity Agreement with the Department of Health and Social Care include:

- The Supplier's details are entered as part of the Master Indemnity Agreement [Register](#).
- 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 and Social Care) is current.

1.32 The instructions for Suppliers that wish to enter into an Overarching Master Indemnity Agreement are as follows:

- 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.
- 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.
- The signed Overarching Master Indemnity Agreement should then be e-mailed to the Department of Health and Social Care at the e-mail address set out in Part D 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 and Social Care executing the Overarching Master Indemnity Agreement.
- Once the agreement has been checked by the Department of Health and Social Care, the Master Indemnity Agreement number is inserted and then signed by Department of Health and Social Care, 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 and Social Care.

- Appropriate details will then be included by the Department of Health and Social Care in the Master Indemnity Agreement Register, as referred to above.
- As the Master Indemnity Agreement Register is updated on a regular basis, Suppliers and Authorities can check with the Department of Health and Social Care (using the contact details at Part D 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.

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

- 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 and Social Care using the contact details at Part D 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 and Social Care; or confirming (b) that there have not been any policy changes that have not already previously been notified to the Department of Health and Social Care. 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 and Social Care terminating the Supplier's Overarching Master Indemnity Agreement and removing its details from the Master Indemnity Agreement Register.
- Following receipt and checking of the information referred to at point 1.33 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 and Social Care to the Supplier as all details can be checked on the Master Indemnity Agreement Register.

Part D - Enquiries and Contact details

- If in doubt about any aspect of the templates or any other parts of this guidance you should contact the Department of Health and Social Care via email at: mia@dhsc.gov.uk in the first instance.
- Completed Overarching Master Indemnity Agreements, any scanned documents relating to the insurance checks carried out by the Department of Health and Social Care 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 and Social Care in relation to any MIA Call-Off Agreement should be sent by e-mail to mia@dhsc.gov.uk.

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