Regulated Study Agreement Preparation - Host

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| Document No.: | GS001-W01 v5.0 |
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| Issue Date: | 10 SEP 2025 |
| Effective Date: | 15 SEP 2025 |

# Foreword

## The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

## This Work Instruction (WI) details the steps required in order to prepare and review trial agreements for regulated studies that are sponsored by parties other than the UoE and/or NHSL.

## For all hosted clinical studies NHSL is likely to be the contracting party but for certain academic and non-commercial studies UoE may also be a contracting party under a tri-partite or multi-partite arrangement.

## The steps detailed in this WI will be undertaken by the R&D Contracts Manager, or Principal R&D Manager (the “Contracts Team”), and assistance may be sought from the UoE Contracts Team and NHSL R&D Governance team as required.

## The decision on whether to put in place an agreement for a hosted study rests with the Sponsor of the study. However, it should be noted that such an agreement is required for all studies that are Clinical Trials of Investigational Medicinal Products (CTIMP) and regulated Clinical Investigations of Medical Devices (CIMD) (study types 1-4 on an IRAS form).

Instructions

## **Trial Agreements**

## 2.1.1 The need for a trial agreement will be identified by the NHSL R&D Governance Reviewer. In addition, NHS Research Scotland Permissions Coordinating Centre (NRSPCC) may upload a draft agreement onto the Scottish Research Database Application (SReDA).

## 2.1.2 The request for a trial agreement in relation to a non-commercial or academic study will be forwarded to the R&D Contracts Manager, who will then be responsible for negotiating and finalising it with the study Sponsor or Sponsor delegate. In relation to commercial studies, the NHSL R&D Governance team shall be responsible for the day-to-day negotiating and finalising of the agreement with the study Sponsor or Sponsor delegate, escalating to the R&D Contracts Manager where support is required.

## **Model Agreements**

### NHSL accepts the published model clinical trial agreements in Table 1 below without requesting any revision or insertion of additional wording. Parties using the model clinical trial agreements in Table 1 must ensure they use the most recent versions of the applicable Model Agreement as published online (see section 3). Agreements and descriptions in *italics* indicate there is an alternate version of the Model Agreement, designed for when a third-party Contract Research Organisation (CRO) is also involved:

## **Table 1: Model Agreements**

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| --- | --- | --- |
| **Model Agreement** | **Parties** | **Description** |
| mCTA (model clinical trial agreement) *[and CRO-mCTA]* | NHSL and Sponsor Company *[and CRO]* | Used for commercially sponsored CTIMP studies *[that involve additional input from a CRO]* |
| mCIA (model clinical investigation agreement) *[and CRO-mCIA]* | NHSL and Sponsor Company *[andCRO]* | Used for commercially sponsored device studies *[that involve additional input from a CRO]* |
| mNISA (model Non-Interventional Study Agreement) *[and (CRO-mNISA)]* | NHSL and Sponsor Company *[and CRO]* | Used for commercially sponsored non-interventional studies *[that involve additional input from a CRO]* |
| mNCA (model non-commercial agreement) | NHSL and Sponsor(s)(this model may be used as a tri-partite agreement where 2 bodies are co-sponsoring) | Used for all academic and non-commercial studies sponsored by charities, academic institutions and NHS organisations that are study types (1-4) on an IRAS Form.  |
| LOID (Local Organisational Information Document)  | NHSL and Sponsor | Used for all academic and non-commercial studies sponsored by charities, academic institutions and NHS organisations that are study types 5+ on an IRAS Form. |
| mC-PICA and mNC-PICA (Sponsor and Site versions) (Model agreements for Participant Identification Centres (PICs)) | NHSL and SponsorORNHSL and Trial Site(There are some instances where we will be acting as PIC direct with Sponsor, or on behalf of another participating Site) | Used to identify potential research participants in a study, without actually being a host of the study or conducting research on site.  |
| mMTA (Model Material Transfer Agreement) | NHSL and Sponsor and/or Sponsor’s agent. | Used when our only role in a research study is the provision of human biological material to the Sponsor (or Sponsor’s agent). |
| Hub and Spoke Agreement (Commercial and Non-commercial versions) | NHSL (as Other Trial Site or Spoke) and Lead Trial Site*OR*NHSL (as Lead Trial Site or Hub) and Other Trial Site(s) | Used in commercial or non-commercial studies, where the Lead Trial Site is not doing all of the research activities, but some activity is taking place at Other Trial Site, all under the supervision of one Principal Investigator based in the Lead Trial Site.  |

NOTE: Any other future Model Agreement not mentioned above that is published on the IRAS Help webpage as a model for supporting documentation shall also be accepted.

## **Information Added to Model Agreements**

### All model agreements will be provided by the Sponsor as the template document populated with Sponsor and study details. The R&D Contracts Manager, or R&D Governance Reviewer (in the case of commercial studies) will review the proposed agreement and provide the following information detailed in Table 2.

## **Table 2: Information Added to Model Agreements**

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| --- | --- |
| Blank | Information to be Added |
| Board name, designation and headquarters address | Lothian Health Board, constituted pursuant to the National Health Service (Scotland) Act 1978 (as amended) and having its headquarters at Mainpoint, 102 West Port, Edinburgh, EH3 9DN, UK (only add UK if the Sponsor is out with the UK) |
| Principal Investigator (PI) details (for academic studies only) | The full name and title of the individual who will be the local PI for the study in NHSL  |
| Signatory on behalf of NHSL | Should be left blank where possible  |
| Number of participants (academic studies only) | The number of expected participants to be recruited in NHSL should be added. This information will be taken from the LOID or indicated by the Sponsor. |
| NHSL notice details | Principal R&D Manager, ACCORD Office, Usher Building, NHS Lothian, 5-7 Little France Road, Edinburgh BioQuarter - Gate 3, Edinburgh, EH16 4UX, UK [only add UK if the Sponsor is out with the UK]. E-mail: loth.accord@nhs.scot  |
| Payment details | Payment by the Sponsor may be made by cheque made payable to: “Lothian Health Board” or by BACS transfer to:“Bank name: The Royal Bank of ScotlandAccount name: NHS LothianAccount number: 00198454Sort code: 83-51-00Payment Reference: [Study Acronym] [PI Surname]”The Payment reference is usually missing on standard published templates, but it is useful for us if a line is added and this is included, under the convention of the study acronym and surname of the PI as above.Remittance should be sent to “Assistant R&D Management Accountants, ACCORD Office, Usher Building, NHS Lothian, 5-7 Little France Road, Edinburgh BioQuarter - Gate 3, Edinburgh, EH16 4UX (E-mail: loth.researchinvoicing@nhs.scot), UK [only add UK if the Sponsor is out with the UK]”. |

## **Non-model Agreements**

### All non-model agreements provided by a Sponsor will be reviewed by the R&D Contracts Manager, seeking and obtaining legal advice from the Commercial Contracts Team at the Central Legal Office (CLO) for NHS Scotland, as required. Approval to refer to the CLO must be obtained from a member of the Contracts Team prior to contacting them.

### Some academic institutions may require that the UoE be a party to the agreement. For example, where the UoE is the substantive employer of the PI. In this case the agreement will be discussed with the UoE Contracts team. If any changes are required to be made to the agreement this will be negotiated with the Sponsor.

## **Negotiation and Finalising Agreements**

### The R&D Contracts Manager is ultimately responsible for negotiating and finalising agreements with a study Sponsor (though this will largely be managed by the R&D Governance Reviewer in the case of commercial studies). In the case of the mNCA, this should be populated with the NHSL details and e-mailed to the Sponsor for final review and approval. Often the Sponsor will only provide a copy of the mNCA in a pdf format. Before acceding to this, the R&D Governance Reviewer should request a copy in Word format to be provided. If the Sponsor refuses this request, the details outlined in the Table 2 should be e-mailed to the Sponsor with a request that they generate the final agreement.

### Once finalised and agreed, commercial Sponsors will take on the responsibility for generating the execution copies of the agreement before sending them to NHSL for signature. In some cases, however, for academic and non-commercial Sponsors, NHSL will be responsible for generating the execution copies of the agreements.

### Once the agreement has been signed, the R&D Contracts Manager will inform the R&D Governance Reviewer that the agreement has been signed and shall file a fully executed copy of the agreement in the appropriate study folder on the R&D shared drive.

## **Execution of Agreements**

### Agreements will only be signed by an authorised signatory of the Board. Authorised signatories are the R&D Director; the Deputy R&D Director; the Principal R&D Manager; and the Head of Research Governance (NHSL). Where the value of a contract warrants additional signature, a member of the R&D Finance or Contracts Team will decide whether an additional signature by the Board Finance Director is required.

### For all CTIMP studies, regulated CIMD studies, and all commercial studies, a fully executed agreement must be in place before the study receives R&D management approval on behalf of NHSL. If an agreement is received signed by all of the other parties, the agreements may be signed on the same day as NHSL R&D management approval is given.

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### Common practice now is for agreements to be signed electronically, using a verified e-signature platform, such as DocuSign or Adobe Acrobat Sign, among others. We can accept these, and in such cases, a signed pdf copy shall be sufficient to regard the agreement as being fully executed. It shall be for the Contracts Team to establish whether an agreement has been validly executed, and request re-signature where required. Where a Sponsor has required a hard copy to be signed, this shall be scanned so that an electronic copy can be retained and filed.

## **Filing Agreements**

### A copy of the fully executed agreement shall be uploaded into the appropriate study folder of the shared drive and named accordingly in accordance with Schedule 1 (Contract Naming and Filing system standardisation). Where a wet ink original of the agreement has been scanned, the scanned copy shall be uploaded into the appropriate folder as above, and the hard copy shall be retained with the Principal R&D Manager.

# References

All of the model agreements referenced in this WI are available at the following website:

<https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#Contracts-Agreements>

Model agreements populated with NHSL details are located on the NHSL R&D shared drive, and on SReDA.

# Schedule 1: Contract Naming and Filing System Standardisation

## **Filing Standardisation**

All signed agreements should be saved in the “Executed Agreements” folder found within the “Finance and Agreements” folder on the shared drive. This is where all fully executed agreements should be saved for ease of reference. All earlier drafts of agreements which are unsigned should be moved into the “Superseded” folder, also within the “Finance and Agreements” folder.

Only agreements to which Lothian Health Board is a party should be saved in the Executed Agreements folder. Collaboration Agreements, Data Sharing Agreements, Supplier Agreements and letters received as part of a document set to which Lothian is **not** a party should not be retained in the Executed Agreements folder.

Additionally, only agreements which are signed by **all** parties should be saved in the Executed Agreements folder. Agreements signed by only one party should not be saved in this folder (unless multiple copies form counterpart signature). Signed Site Agreements where a copy of a signed PI Declaration has been signed separately can be saved in the Executed Agreements folder, alongside the separately signed PI Declaration.

## **Signed Contract Naming Convention**

All signed agreements should be named in the same way moving forwards. The format should be “IRAS” and the IRAS number, followed by the type of agreement, followed by “FE” (to signify the agreement is Fully Executed, as opposed to just signed by one party), and ending with the date the agreement was signed, each separated with an underscore. See below:

IRAS [studynumber]\_[Type of Agreement]\_FE\_ddmmmyyyy

*(For LOIDS, the words “LHB authorised” should replace “FE”).*

To illustrate this, the following examples have been generated:

IRAS210424\_Site Agreement\_FE\_01Feb2025

IRAS210424\_Site PI Declaration\_FE\_07Feb2025

IRAS271014\_Collaboration Agreement\_FE\_31Oct2024

IRAS221012\_Variation Agreement No.1\_FE\_12Oct2027

IRAS111108\_PIC Agreement\_FE\_13Jun2025

IRAS131289\_LOID\_LHB authorised\_30May2025

## **Standardised terms:**

When naming files in the Executed Agreements folder, the following standardised terms and formatting should be used for consistency, and to avoid any confusion:

* Dates – ensure dates are in the format of DDMMMYYYY, such as 01Feb2025. This will avoid any confusion of electronically signed agreements which may be in a US or UK date format for clarity.
* “FE” – fully executed should be used instead of “signed” to indicate both (or all) parties have signed, rather than only one (or some) and that the contract is final.[[1]](#footnote-1)
* “Site Agreement” – should be used for all site agreements regardless of the particular template contract used to create the site agreement (mNCAs, mCTAs, mNISAs etc.)
* “Variation Agreement” should be used in place of ‘Amendment Agreement’ or any other alternative, for consistency and so that Site Agreements show before Variations in the shared drive. A Variation Agreement is exclusively deemed to be a variation to the Site Agreement, unless otherwise specified (i.e. “Collaboration Agreement Variation 1”).
1. The only exception to this is where a non-commercial agreement has been signed by Site and Sponsor(s), but not the PI Declaration. This agreement can be regarded as FE, and the signed PI Declaration can be signed and filed separately (if applicable). [↑](#footnote-ref-1)