Standard Operating Procedure			**52.004**
R&I Contract Development and Review			
Version	5.0		
Prepared by	Ross Nicol	Signature	Date
Approved by	Melissa Robert	Signature	Date
Released by	Julie Brittenden	Signature	Date

1. SOP Category
NHS GG&C Hosted R&I

2. Staff Category

Staff Category	R	A	C	I
Systems Manager		X		
Sponsor Research Co-Ordinator	X			
Commercial Research Co-Ordinator	X			
Research Facilitators	X			
Senior Research Administrators	X			
Research Administrators				X

3. Scope
This procedure applies to NHS Greater Glasgow & Clyde (NHS GG&C) R&I Department.

4. Purpose
To describe the procedure for negotiating, and executing (accepting) contracts for research projects to comply with EU Directive, Medicines for Human Use (Clinical Trials) Regulations 2004 and UK Policy Framework for Health and Social Care Research.

5. Procedure
Contracts set out obligations that the law will enforce and manage risk for each party. Thus, NHS GG&C should use contracts to formally confirm arrangements with Sponsors, CROs, Research Sites and vendors to ensure that all responsibilities, finances and work schedules (protocols) are agreed before R&I approval is given. In some instances, contracts may be initiated post approval e.g. if a new Vendor is identified post approval. In the event the services of a vendor are required, they must first be approved for use by following SOP 51.015 prior to issuing a contract.

The Research Co-ordinator or Research Facilitator will identify whether there is a requirement for a contract(s) and the contract type(s) (ref SOP 52.002 Obtaining NHS Management Approval for commercial Studies, SOP 52.001 Obtaining NHS Management Approval for non commercial process.) The Research Co-ordinator or Research Facilitator may receive a contract from other parties or may be asked to generate the contract for the other party. The use of the National NHS template contracts should be encouraged at all time, these can be found on the IRAS web page www.myresearchproject.org.uk/help/hlptemplatesfor. For non-commercial Glasgow Sponsored studies the list of common contracts that have been agreed can be found in the common drive common\1.Systems\Contracts (Sponsor Team) Using compare document function in MS Word can aid the comparison of the contract received and the National NHS template.

Contracts that have modifications to the National NHS templates should be reviewed against the unmodified version of the agreement. Content of specific clauses should be considered based on the perceived risk to NHS GG&C as a Board. In the event that a particular contractor wishes to use a clause or clauses which contradicts the National template or the Research Co-ordinator/Facilitator does not understand the rationale for the requested change they should bring the issue to the R&I committee for discussion with peers, and Management. Thereafter, legal advice can be sought.

The Central Legal Office employ a number of Lawyers who act on behalf of the NHS. When required, CLO can enter into contract negotiations on behalf of the Board e.g. NHS GG&C Co-sponsor agreement. The inclusion or omission of specific clauses is dependent on negotiation and agreement of all contracting parties.

5.1 Legal Entity

For all NHS GG&C contracts, each party entering into a contract must be a legal entity. For NHS GG&C the legal entity is:

> **GREATER GLASGOW HEALTH BOARD,** constituted pursuant to the National Health Service (Scotland) Act 1978 as amended having its headquarters at J B Russell House, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH (hereinafter Known as the "Board")

If a research project is with a Sponsor out with the UK then the Research Co-ordinator has to ensure the Sponsor has a UK address or has delegated sponsorship duties to a UK representative.

5.2 Study Details

The Research Co-ordinator has to ensure that the correct research title, NHS GG&C investigator, and the agreed number of patients to be recruited have been entered into the body of the contract. The task of updating the contract with this information can be delegated to staff with Administrative responsibility. However, the responsibility to ensure that the information has been updated and is accurate remains that of the Co-ordinator. The recruitment target should be discussed with the research team and a realistic target number agreed to ensure that the Board can deliver. The study Protocol is often appended to the study contract as an appendix or schedule depending on who has initiated the contract.

5.3 Liabilities and Indemnity

For clinical trials involving medicines it is a legal requirement that there should be insurance or indemnity to cover the liabilities of Sponsors and investigators. For other research projects NHS GG&C must ensure that the Sponsor has insurance to undertake the study.

NHS GG&C will warrant that it is a member of the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS). However, NHS GG&C is unable to provide indemnity for non-negligent harm but may consider ex-gratia payment on a case-by-case basis. In exceptional circumstances NHS GG&C can purchase additional insurance cover. This would only occur for multi centre, multi country studies and again would be considered on a case-by-case basis.

For Commercially Sponsored CTIMPs and medical device studies, NHS GG&C expects minimum insurance cover of £5 million or its equivalent if in foreign currency. Other levels of insurance should be agreed on a case-by-case basis and the Research Co-ordinator may bring the level of insurance to the R&I committee (and Management team) for discussion and consideration.

NHS GG&C insurance (CNORIS) does not cover non-clinical liabilities which might arise from intellectual property rights, confidentiality or data protection claims and; therefore, a cap on the NHS GG&C liability should be ensured in line with clause 5.4 and 5.5 of the BIA Clinical Trial Agreement 2011 version:

> "5.4 NHS GG&C's liability to the other party arising out of or in connection with any breach of the contract or performance of the research project should not exceed the amount of fees payable by the other party under the agreement."
>
> "5.5 In respect of any wilful and or deliberate breach by the NHS GG&C, it's liability to the other party should not exceed twice the value of the contract."

For non commercial CTIMPs that NHS GG&C host, the Research Co-ordinator should ensure that the NHS or University Sponsor indemnifies NHS GG&C. When in doubt of the insurance level provided by the Sponsor, the Research Co-ordinator should seek advice from Senior R&I Management.

For non commercial research where an external organisation is providing the investigational medical product, the external organisation manufacturing the investigational medical product should indemnify and hold harmless the other parties against any claim brought by a subject in respect of injury arising from the manufacturer failure to comply with Good Manufacturing Practice (as per Clause 5.4 of mICRA).

5.4 Archiving

For all contracts that GG&C enter into, there has to be an agreement that once the study has finished, one of the parties takes responsibility to archive the trial files. The duration of archiving is dependent on the study type and the patient group recruited. Within the model non commercial contracts the archiving arrangements are highlighted in Schedule 2 of the Division of Responsibilities. In general, archiving for non-commercially sponsored studies is delegated to each site. For commercial studies the archiving should be discussed and agreed. Normal arrangement are that the Commercial Sponsor will pay the Board an archiving fee (per box of archiving and for the duration of the archival period) and the Board will organise for the archiving to be arranged to be sent to the Board's contracted facility (i.e. Iron Mountain). Alternatively the Commercial Sponsor may take on the responsibility to arrange for the uplift and archival of all of the study-related documents (this is rare).

5.5 Confidentiality

When a model contract is not used a Confidentiality clause should be inserted into all contracts. Confidentiality should cover confidential information, medical confidentiality, data protection and Freedom of Information Act (Scotland) 2002 for all parties. The clauses of the template should be used as reference along with discussion with the investigator R&I management. Several Pharmaceutical organisations and CRO opt to enter into a Confidentiality agreement with the Board and submit a Confidentiality Disclosure Agreement (CDA) in advance of sharing the study protocol and details. CDAs are reviewed and signed off (at Co-ordinator level) in advance of study documents being received by the Board.

5.6 Data

For all contracts that NHS GG&C enter into, the Co-ordinator must check if there will be any data or document transfer involved in the study. If so, it is essential that the requirements for data and document transfer and retention are addressed in the contract. This includes how the data or documents will be sent to the recipient, what the recipient will do with the data, the retention period for the data and whether the data will be destroyed after this period or returned to the Sponsor. Where this clause is not applicable, this will be noted in the contract.

5.7 Publications

NHS GG&C has a responsibility to ensure appropriate publication and dissemination of clinical research for the benefit of patients and their peers.

This clause should indicate the conditions that govern the way in which individual investigators should prepare their publications, and the opportunities they should allow Sponsors to comment on the publications. It should also specify the timeline available to Sponsors in which they can protect their intellectual property (if applicable).

5.8 Intellectual Property (IP)

When a model contract is not used a clause on intellectual property and a provision of knowledge should be inserted into all contracts to ensure that the inventions, ideas, know-how, foreground and background IP are protected. The clauses of the template should be used as reference along with discussion with the investigator and R&I Management team if required.

5.9 Notices

For contracts that have a notice clause (a notice clause states how the parties to a contract will communicate with each other in written form). Notices tend to related to contracts amendments of billing enquiries in relation to contract payments and milestones. The correct address for the notices to be sent to in NHS GG&C is:

(Name of Research co-ordinator)
R&I Management Office
NHS Greater Glasgow and Clyde
Ward11
Dykebar Hospital
Grahamston Road
Paisley, PA2DE

5.10 Governing Law

All contracts should be made under the jurisdiction of Scots Law in the first instance. The reason being if the contract is challenged legally then court proceedings will be held in the Scottish Courts under Scots Law and NHS Scotland solicitors tend to only be qualified in Scots Law.

If the contracts are made under any other law then the NHS will have to pay for solicitors qualified in the law of the country detailed in the study contract. However, GG&C have entered into contracts signed under English and European law when contract negotiations have halted over this matter. If in doubt, the Research Co-ordinator should escalate this to the R&I Committee and Management for consideration. Thereafter, they may seek legal advice from the Central Legal Office.

5.11 Authorised Signatories

NHS GG&C research contracts should be signed and dated by authorised signatories for the Board. For research contracts this is currently the R&I Systems & Operations Manager, Lead Trials Pharmacist, Senior R&I Manager and R&I Director. Once a contract is executed and posted or emailed it is legally binding.

5.12 Timelines

The R&I Co-ordinator should ensure that the agreed timelines for deliverables are correctly entered in the study contract.

5.13 Roles and Responsibilities/Work Schedules

Within all contracts any additional roles and responsibilities of each party should be entered into the agreement as an appendix, this could be in the form of a protocol, work schedule or list of roles and responsibilities for each party.

5.14 Financial Appendix

The Research Co-ordinator has to ensure that any funding amounts agreed between the contracting parties (SOP 52.002 Commercial approval process, SOP 52.001 Obtaining management approval non commercial) have been correctly entered into the contract. Value Added Tax (VAT) must be mentioned to ensure both parties are aware the amounts are either including or excluding VAT. Expert advice can be received from R&I Finance Accountants if required.

The NHS GG&C bank details should be added as follows:

Bank name:	Royal Bank of Scotland
Bank address:	10 Gordon Street, Glasgow G1 3PL, United Kingdom
Account Name:	NHS Greater Glasgow & Clyde
Sort code:	83-07-06
Account No:	10542386
IBAN:	GB30RBOS83070610542386
BIC:	RBOSGB2L

Details of where invoices should be sent to and relevant reference numbers should be added. Send remittance advice to:

Finance Administrator
R&I Finance Department
Ward 16
Dykebar Hospital
Grahamston Road
Paisley, PA2 7DE
Scotland, UK

Tel:
Fax:
Email:

The study reference number GXXXXXXXX should be stated on all payment correspondence.

5.15 Amendments

For amendments to contracts the same principles should apply and reference should be made to the original contract. The Research Co-ordinator should review the amendment in conjunction with the original contract and take a view as to whether the amendment requires that the study contract be updated to reflect this.

5.16 Documenting contract review

For CTIMPs Sponsored or Co-sponsored by NHS GG&C a template of contract review and details of any amendments to standard contract clauses must be captured in Form 52.004A (Contract GCP Review Checklist). Consideration will be given to the principles of GCP when reviewing CTIMP contracts and all other study-related documentation.

6. Referenced documents

- UK Policy Framework for Health and Social Care Research
- SOP 51.015 – Assessment of Vendors
- SOP 52.002 Obtaining NHS management approval for commercial studies
- SOP 52.001 Obtaining NHS management approval for non commercial process
- Form 52.004A - Contract GCP Review Checklist

7. Related Documents

N/A

8. Document History

Version	Date	Description
1.0	07/03/2013	Release of first version
2.0	14/07/2016	Updated to template v1.4.
3.0	18/03/2020	Temp. Change to Author and "Approved by". Change to "Released by". Procedure updated to reflect current practice and minor typographical changes. Contract notices updated to reflect change in address. Creation of section 5.15 to record review of specific trial clauses (suggestion from audit finding). Version updated.
4.0	26/11/2020	Updated to include data transfer and retention in contract review process. Inclusion of a statement about contract negotiations. Version updated.
5.0	10/03/2023	Update correct Form name and version – Form 52.004A Contract GCP Review Checklist.