St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Standard Operating Procedure (SOP)

Preparation and Approval of St George's Research Contracts

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	New SOP	Sebastian Sethe
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1. Background

Sometimes the distinction is made between **agreements vs. contracts**. In this sense, an agreement is a (sometimes tacit) understanding about the conduct of a project that is not necessarily regarded as 'legally binding'. However, these 'non-binding' agreements can attract legal relevance where they form part of the evidence about the intentions of the parties in a presumed contract or in order to establish liability. Thus, in a clinical research context, focusing on the distinction between agreements and contracts is not always useful. Instead, it is important to establish that all relevant stakeholders are clear about what is expected to be done by whom and if that expectation is not met, how that failure will be identified and addressed.[1]

Often there is a **protocol** governing the research. This protocol and any amendments to it should not be in contravention to any specification in other agreements. However, the legally binding contract would prevail as an indication of the parties' intentions even if it expressly contradicts the protocol. Contracts should therefore be non-specific regarding operational requirements and incorporate the current respective version of the protocol by reference.[2] Where St. George's agrees to abide by a protocol that may be amended from time to time, St. George's should reserve the option to review such amendments prior to implementation and retain the power to either veto the amendment and/or to terminate the agreement with no detriment to it or trial participants.[3] As a Sponsor, St. George's must always reserve the right to review and approve any suggested changes to the protocol as per Management of Amendments SOP JREOSOP0011.

A **delegation log** further establishes domains of responsibility. Sometimes, a general delegation roster is part of, or appended to a contract. Again, care should be taken that delegations are not contrary to the contract or any other agreements, but more importantly, a simple assignment matrix may need substantiating regarding details and oversight.[4]

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[1] Example: St.George's as Sponsor will usually enter into an agreement with the CI where the CI is a St.George's employee. Where the CI is external to St.George's a contract would be applied instead. In either case however, the main factor will be to establish clarity and certainty regarding the responsibilities of the CI.

[2] Example: The St.George's model contract expressly acknowledges the primacy of the contract, but incorporates the protocol as binding the parties. A change to the protocol that conflicts with the contract (e.g. in agreed timelines) would require an amendment of the contract.

[3] The St. George's model contract expressly acknowledges the primacy of the contract, but incorporates the protocol as binding the parties. A change to the protocol that conflicts with the contract (e.g. in agreed timelines) would require an amendment of the contract.

[4] Example: The Model agreement lists the responsibility to "Report suspected research misconduct" with both "Sponsor and NHS Organisation" – the intention behind the formula may be clear, but in the absence

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St. George's has a clear preference to be legally bound as an institution only by those who are authorised to commit the institution – the **authorised signatories**. However an agreement entered into by someone else (ostensibly) on behalf of St. George's or an agreement that has not been signed cannot automatically be considered invalid. The decisive factors will be whether institutional oversight was required and discharged according to the relevant SOP and whether there is any ambiguity or uncertainty related to the responsibilities agreed on. Conversely, St. George's has to assume that those who sign contracts for other parties are authorised to do so. It is not practical to demand evidence that such authorisation exists. This is only indicated where there is doubt about the legitimacy of a signature.[5]

St. George's Hospital Medical School (also doing business as St. George's, University of London) and St. George's University Hospitals NHS Foundation Trust have agreed a **Memorandum of Understanding for Research**. In this, both institutions have agreed to act jointly in the context of clinical research wherever appropriate and confirmed a framework under which to conduct research activities. Based on this agreement, contracts in a clinical research context binding either institution are also immediately relevant to the other. Where practicable and appropriate, other parties should be made aware of this relationship and agreements should be entered on behalf of both institutions jointly.

Integration with other policies: Where relevant, contract initiation must take account of applicable institutional policies including, but not limited to:

- The St. George's Memorandum of Understanding on Research
- Trust Standing Orders and Standing Financial Instructions
- Trust Procurement Policy and Tendering procedures
- University Financial Regulations
- University Procurement Thresholds and Tendering Procedures
- University Standard Terms and Conditions (Procurement)

Contracts should also take appropriate account of European Directives Governing Public Procurement and guidance from the Department of Health

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of more specific arrangements the stipulation is insufficiently precise: What qualifies as misconduct? How will the Sponsor learn that the site 'suspects' and vice versa? Who shall the reporting be made to? What are the timelines to investigate alleged misconduct? Is there an obligation to halt the trial? What are the financial implications?

[5] As an example, where an institutionally binding signature has been provided by someone known to be a student, or where the person signing the document on behalf of one organisation gives an address and communicates using the letterhead of a clearly different organisation.

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Where there is one or more funding sources, contracts must take account of any express or implied stipulations by the funder.

Where another party seeks to refer to its **standard policies & terms** these should be reviewed for compatibility where the reference is central to the understanding between the parties. It is not practical to review a full suite of institutional policies referenced in an agreement. NHS and public sector institutions in the UK can be assumed to share general standards and values. Compliance of all contracting parties with applicable law and regulation can always be assumed and only requires review where there is cause, as part of a random check or similar exercise or during subsequent monitoring.

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JREO acts as the representative of both St George's University of London (SGUL) and St St. George's University Hospitals NHS Foundation Trust(SGHT). St Georges will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This Standard Operating Procedure covers general and specific aspects of managing contracts in a context where St. George's is assuming the role of 'Sponsor' of research project.

Compliance with this SOP is required where St. George's is assuming the role of 'Sponsor' in a Clinical Trial of an Investigational Medicinal Product. In all other cases compliance with this SOP is recommended.

4. Definitions

4.1 Contractor

Any Party external to St. George's with whom a contract or agreement is sought or made.

4.2 JREO Liaison/Chaperone

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A person, usually a JREO Research Governance Officer, who coordinates the review by different JREO departments, the other party and the signatory. This is not a formal role and may change in-process based on who is best placed to progress the matter. If in doubt, the Liaison/Chaperone should be explicitly nominated.

4.3 Chief investigator (CI)

The leading investigator responsible for the overall conduct of the clinical trial or study at all the sites.

4.4 CTIMP

A clinical trial of an investigational medicinal product (IMP), often known as a drug study. The IMP is a pharmaceutical form of an active ingredient or placebo being tested or used as reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. (Good Clinical Practice 1.33)

4.5 JREO

The JREO is the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust.

5. Responsibilities

This SOP is to be followed by the JREO and the Chief Investigator (CI) of the proposed study.

It is the responsibility of the Head of Research Governance (HRG) of the JREO to ensure that this SOP is updated by the review date or as necessary.

It is the responsibility of the CI to ensure that they have read and understood the JREO SOPs and ensured that their team familiarise themselves with the SOPs. It is also their responsibility to ensure that they check that they are working with the most current version of the SOPs

JREO officers have responsibilities to review draft contracts within their allocated scope, and to seek assistance for review within that scope.

5.1 JREO Review

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a. Finance. Is the agreement sound from a financial point of view? Is it good value for money? Have financial procurement guidelines been followed? Have all important cost factors been considered? Have personnel costs been addressed at the correct salary level? Have the appropriate overheads been applied? What are the financial implications of continued treatment or employment beyond the trial? Are the arrangements for VAT appropriate? Are the arrangements for invoicing clear and workable?

b. Governance. Is the proposed trial design feasible from an organisational perspective? Are the recruitment criteria appropriate and appropriately checked? Is the process for informed consent appropriate? Have arrangements for confidentiality and data protection been considered? Does the trial involve sensitive participant populations or research areas and what are the implications? Will the trial involve changing patient care pathways, or implementing new clinical procedures?

c. Enterprise. Are intellectual property opportunities identified? Are licenses to background IP appropriately identified and incorporated? How will arising IP be identified? How is ownership of arising results arranged? Have other ownership rights been addressed? Will the agreement impact on existing commercial or other relationships?

d. Legal. Does the contract comply with UK law? If laws of other countries are incorporated, is this warranted? Are the liability and indemnity arrangements appropriate? Are mechanisms provided for the effective resolution of complaints and disputes? Has the RCE reviewed unfamiliar contractual 'boilerplate'? Where required, legal services should be obtained on a subcontract basis from external solicitors, or via the Trust membership of the NHS Litigation Authority as appropriate.

e. Pharmacy Review: Can the IMP be procured from normal pharmacy stock within its Marketing Authorisation? Have factors like Importation licensing; QP release, storage, packaging, labelling, shipping, recall shelf-life extension and safety reporting, been appropriately addressed?

5.2. Signatory Authority. The following roles or their designated deputies are the designated authorised signatories for contracts in the context of this guidance note. With the exception of hand amendments, individuals should not sign a contract that they have substantially negotiated themselves.

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Contract	Signatory	Alternate
Contracts binding both SGUL & SGHT	Head of Research Governance	Dean of Research & Enterprise
Contracts binding SGUL	Head of Research Governance	SGUL Chief Operating Officer (COO)
Contracts binding SGHT	Head of Research Governance	SGHT Associate Medical Director (Research)
Acknowledging trial-related responsibilities	CI / Team Leader	JREO Sponsor Representative

6. Procedures

6.1 Drafting & Templates

The Research Contracts Executive (RCE) drafts and continually revises a suite of template agreements that form the basis for further use at the JREO. (These are based on nationally agreed model contracts including the DoH approved 'Model Agreements' suite for clinical trials and the 'Lambeth' and 'Brunswick' model agreements for academic collaborations.)

The RCE can advise on the **appropriate template** to use. Decision aides and in-draft explanatory notes may also be provided.

For CTIMPs sponsored by St. George's no templates should be used without JREO oversight.

Templates have a 'substance' and a space for 'details'. The former is often but not always fairly generic, the latter includes variable elements such as exact amounts and prices, dates, names and similar. Usually, a template identifies the space for adjusting details unambiguously, but if there is doubt whether a proposed detail affects the 'substance' of the template, the RCE should be consulted.

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Un-amended approved contract templates, with the relevant details filled in, can be used by any JREO RGO. If there is doubt about the appropriateness of the template for the task, the RCE should be consulted. No template should be amended in its substance without consulting the RCE.

Templates are **version** controlled in the footer, with a designate template review date and schedule. The current operative version is kept electronically at a single file location and superseded versions are immediately withdrawn by the RCE. No copies of templates must be kept separately by JREO officers. Responsibility for updating templates rests with the RCE taking account of feedback from all stakeholders and arranging for such specialist expert advice as may be required.

The RCE shall provide training to JREO staff about the features, management and points to consider in the existing templates at least annually.

For trials with many NHS sites St. George's prefers to use the UK **model clinical trial agreements** (mCTA/MICRA) endorsed by the Department of Health. Where appropriate, amendments to these agreements should be kept to a minimum in order to facilitate speedy review and adoption.

Where **no appropriate template** exists the RCE will draft appropriate agreements.

For CTIMPs sponsored by St. George's, all agreements proposed by the other party require RCE review.

6.2 Selecting a Contractor

The institutional policies (referenced in 1 above) regulate the vetting and assessment of prospective contractors and suppliers.

In the context of a clinical trial further or **alternative assessment criteria** may be applied in selecting a contractor. These can include questionnaires, assessment of CVs and references, assessing quality systems and certificates. It is also permissible, and this option is often used, to refer to prior experience with the contractor or to the general reputation of the contractor in other clinical trials.

The pre-contractual scrutiny should be **risk-adjusted** based on the capacity of the contractor to imperil the safety of trial participants or data integrity.

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NHS trial sites in the UK can be expected to conduct a feasibility/capacity assessment as part of their 'R&D review' process, obviating a need for separate pre-contract assessment. Any open issues should be resolved prior to site initiation.

The basis for determining the suitability of a contractor should be indicated on the contract memo and supplemented with further detail in separate documentation where indicated.

6.3 Negotiation

Any JREO RGO can contribute to contract negotiation. A 'contract chaperone' (the JREO liaison) should be agreed whose responsibility it is to bring all relevant departments together and drive the contract negotiation process to a timely conclusion.

Where drafts are exchanged, it is useful to '**lock**' documents so that only 'tracked changes' are possible.

Negotiations should be conducted **in confidence**. It may be appropriate to cover this separately with a prior confidentiality agreement and/or to extend the period of confidentiality to which a contract relates into the negotiation period.

Where a negotiation does not result in a contract, it may not always be possible to identify a clear point when the negotiation was **abandoned**. Where possible a note should be made to that effect. Open negotiations that have not progressed for 3 months without apparent reason for the pause should be considered as abandoned.

Records of negotiations should be kept. However, only statements made that have an important bearing on the interpretation of the subsequent agreement (or explain the reason for not entering into an agreement) need to form part of the JREO trial folder. It is also useful to record particularly controversial or protracted points. Where in doubt, the RCE should be consulted.

6.4 Review

Aspects that are usually considered in reviewing any proposed contract and agreement are listed under the respective field in Responsibilities, above.

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6.5. Execution

St. George's has no preference as to the **order of signatures**. First signature has the advantage that the review of the final version can be expedited and eliminates the need for post-signature checking; final signature has the advantage of being able to control execution.

Where the other Party is issuing the final version (and usually supplying first signature), the JREO Liaison needs to **check the issued copy** against the final agreed draft. Usually, this check is documented by signing or stamping each page of the agreement.

Where St. George's is issuing the final version for signature, the agreement should also be **marked on each page** (either via stamp or a unique reference code as part of the printout) to record that each page has been reviewed and to ward against inadvertent or wilful modification.

The practice of only circulating **signature pages** should be avoided. Where this occurs, the signature page must contain clear reference to the version draft of the agreement to which it pertains.

St. George's does not operate an 'original' or '**wet ink**' signature policy. This concept has no basis in law and introduces unnecessary risks of confusion and delay. Photocopied and scanned copies are equally acceptable provided the copy is of serviceable quality. Faxed copies are acceptable but should be avoided. Where a Collaborator requests a 'wet ink' hardcopy, the request will be accommodated where possible, however, as Sponsor, St.George's must not endorse any situation where only 'wet ink' signatures are deemed acceptable, unless there is a clearly documented reason why this is required and merited.

The JREO liaison should draft an accompanying **memorandum** that summarises the background and potential idiosyncrasies with the agreement as well as a recommendation for signature or otherwise. The memorandum should incorporate feedback from all responsible departments. It is good practice for the signatory to date and initial the memorandum as seen. Where possible, the memorandum should be returned with the agreement and remain linkable to it for internal reference.

The authorised signatory has the **final responsibility** for reviewing agreements. A signatory should never sign an agreement where they feel unclear about the nature of the agreement to be signed.

Where the liaison or any contributing department **advises against signature**, the authorised signatory should document that the objection was assessed and the reason for disregarding it.

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Agreements may contain a space for investigators and other personnel to sign in **acknowledgement**. This signature can be regarded as optional where it can be demonstrated that the acknowledgement has already been rendered.[6]

To avoid ambiguity, contracts should contain an **effective date** from which point the contract is deemed effective. This date can be before or after the date of last signature, and this will often be indicated to cover, e.g. initial work and to extend the confidentiality cover of the contract to the initial discussions. It is not permissible, however, to select a date for agreement execution ("agreement made on") that is not the actual date of execution. The effective date of the contract cannot be used as a log for the commencement of actual activities. Where relevant, these dates must be recorded separately. Where no effective date is given, the contract is deemed effective from the date of execution: the date when the last required signature (not a signature 'in acknowledgement') was rendered.

Where another institutionally binding signature (rendered by a Director or Executive) has been applied this should be noted and reviewed by the designated signatory.

Where another signature has been applied, and the institution considers itself bound by it, this should be noted and reviewed by the designated signatory.

6.6 Contract Operation

Once a contract is executed it should be shared with and remain readily available to all relevant stakeholders. An electronic copy should be filed in the Investigator file under the name of the local PI, and stored in the REDA database folder for that study under the section 'Documents'.

It is the responsibility of the CI to ensure that everyone with contractual responsibilities is aware of these and has access to the signed agreement where necessary and to ensure that the requirements of the agreement are being met.

In order to maintain effective oversight, consideration should be given to including contracts and Contractors in monitoring plans and activities.

Where a difference in interpretation of a contractual provision becomes apparent, the RCE should be informed straight away. The dispute must be assessed regarding its potential impact on the contractual relationship, on the safety of participants, the integrity of trial data and the overall prospects of the trial.

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[6] E.g. by signature of a funding application or trial protocol that is a faithful reflection of the stipulations in the agreement, or a more detailed description of the duties entered into via the agreement.

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It is the responsibility of the CI to ensure that contracts and agreements reflect current practice, are not expired and are amended, renewed and terminated as appropriate. The JREO does not have capacity to subject all contracts and agreements to periodic review but may flag specific agreements as requiring such review.

6.7 Contract Amendments/variations

The responsibility to identify the need to amend existing agreements rests with the CI in consultation, as required, with a JREO liaison. The JREO SOP on change management (JREOSOP0029) should be considered in this context.

Each proposed amendment needs to be **evaluated** by a competent person or persons regarding the reasons for implementing the change, considering unintended negative consequences related to the change (e.g. by conducting a risk assessment), ensuring that any disruption to current practices will be accounted for and that the change will be communicated to all relevant stakeholders.

It is recommended that any evaluation of **protocol amendments** should include an assessment of the potential impact on any existing agreements and identify the need for new agreements. The JREO SOP on management of amendments should also be followed (JREOSOP0011)

Amendments may take the form of issuing a full new version of the entire Agreement or specify the sections to be altered. In either case the old version in the Trial File should be **marked as superseded** in part or entire and the date noted also. Where a copy is kept in other places, similar filing arrangements should be followed and reviewed upon monitoring.

Hand amendments are handwritten amendments to the typewritten contract, normally after at least one party has already signed. They should be confined to minor corrections. They must be dated and initialled by the RCE or the authorised signatory.

6.8 Termination & Archiving

Often the provisions for the termination of agreements are provided for in the agreement itself. Agreements are deemed largely concluded upon trial end date, but it is important to remember that many contractual stipulations persist past trial closure and may regulate e.g. the publication of results.

Agreements can become **void** or meaningless due to changes in circumstance. The RCE should be consulted to discuss the implications if this occurs.

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Agreements that end **prior to trial end date** whether terminated prematurely or not should be marked as concluded in the Trial File, and any implications from the end of the agreement should be managed as required.

Agreements are not always **essential documents** (as per 31a SI 2004/1031) but they should nonetheless be filed and archived in the same manner wherever appropriate. The minimum requirement for archiving agreements is 5 years. Often this period will be longer where a contract forms part of the TMF. Please refer to the JREO SOP on archiving (JREOSOP0016)

6.9 Special types of agreement

Agreements are sometimes categorised according to type, and are discussed here. However, it is not always useful to treat these different 'types' of agreement as distinct - each agreement can regulate provisions that go beyond the remit indicated in the title.[7]

If different agreements relate to the same project or are linked in other ways, a reference should be made in the agreement or a note should be affixed to the documentation related to the agreement.

6.9.1 Confidentiality agreements. Often called a Non Disclosure Agreement or Confidential Disclosure Agreement (CDA), these are often entered into prior to other agreements to cover the initial discussions between the parties. For this reason it is not normally acceptable to include in the CDA's provisions that govern confidentiality 'in case the trial goes ahead'. Instead, these provisions should be taken up again in a subsequent trial site agreement or equivalent.

6.9.2 Co-sponsorship & legal representative agreements: In these agreements, a clear attribution of responsibilities is even more important than usual. However, where St. George's assumes the responsibility as co-sponsor or sponsor representative, careful consideration must also be given to the contingency of the other party not performing its allocated role and to the consideration that the inter-party arrangement may not be clear to other third parties.

6.9.3 Service level agreements (SLA) and Technical Agreement (TA). There is no agreed legal meaning to these terms. Sometimes, a SLA/TA is held to be a 'weak' form of contract, sometimes it is the opposite- a very specific set of technical instructions as may not be found in a typical contract. Sometimes a "Master Service level agreement" exists

[7] e.g. a materials transfer agreements often contains provisions for confidentiality

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as an overarching contract of general terms between frequent collaborators. In this case, trial-specific details, roles and responsibilities should be further defined in other documented agreements referencing the 'master' agreement.

6.9.4 Orders for the supply of an IMP: Where an IMP can be procured from normal pharmacy stock within its Marketing Authorisation, a separate agreement may not be required. Importation requirements must be considered where required. Of particular importance is the role of the Qualified Person in IMP release. St. Georges as Sponsor must not interfere with this process. Good Manufacturing Practice can be required by reference to established regulatory standards but aspects like Good Distribution Practice, packaging, labelling, and recall procedures, may need specific arrangements. Research Pharmacy may be consulted on these aspects.

6.9.5 Material Transfer Agreements (MTAs) govern the transfer of materials between parties. These agreements are especially important where sensitive material is transferred e.g. personally identifiable information, genetic material and human tissue samples (Contrary to some assumptions, there is no legal requirement under the Human Tissue Act to have MTAs in place). MTAs need only to contain provisions to establish clarity regarding the conditions of and responsibilities for transfer, but where the agreement operates by itself it also needs to incorporate provisions regarding the further use of the material, intellectual property, financial aspects, insurance etc. Where material is transferred as part of a larger project that is subject to other agreements, it is often useful to incorporate provisions on material transfer into these in order to avoid duplication and inconsistencies. As long as the transfer is sufficiently well described in a governing document or protocol that is subject to agreement, a MTA does not need to be a separate document or provision.

6.9.6 Site Agreements. These are agreements with the organisation overseeing a location where interaction with trial participants occurs (usually hospitals or GP surgeries). Site Agreements should only be signed when the Site is confirmed to have met the entry criteria for the trial, however, it is not necessary to have achieved 'NHS R&D approval' at the Site. (It should be remembered that the agreement will be binding unless the requirement for 'NHS R&D approval' is expressly made a condition of the agreement). Site Agreements should incorporate a provision for IMP supply. There is not normally a requirement for the site to request a copy of the MA (IMP)/QP certifications from the Sponsor as these are part of the regulatory application.

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6.10 Specific Issues

6.10.1 Insurance: It is the Sponsor's responsibility to ensure there is provision for indemnity or compensation (via an appropriate insurance policy) in the event of injury or death attributable to a trial. The default position will therefore be that St. George's must be able to cover such events by itself and drawing on insurance and indemnity contractually required from a collaborating Contractor is only a secondary measure to defray financial risk. Therefore, to facilitate contractual obligations, a copy of the relevant policy (or evidence of sufficient assets to cover liabilities arising) must not normally be provided. It must be requested where St. George's as a Sponsor, is by itself categorically unable to provide the requisite cover without drawing on the Contractor.

6.10.2 Subcontracting by the Contractor: It is common custom to require Contractors to seek Sponsor consent before subcontracting any part of the contracted work. However, this is not a requirement in law and the failure to seek this consent does not automatically constitute a breach of GCP. This is the case not least because 'subcontracting' is in itself not an easily identifiable activity in a modern healthcare setting. Where a Contractor has assumed Trial-related duties in a legally binding manner the Contractor remains responsible to the Sponsor for those duties whether it delegates them further or not. Subcontracting is only unacceptable if the Contractor Site is incapable of holding the subcontractor to at least the equivalent of in-house standards. Nonetheless, requests for subcontracting should be logged and may necessitate an amendment to the contract.

6.10.3 Referencing contracts

The usual linking reference for contracts at the JREO is the project reference number composed of, where available, the name of the Principal Investigator, a grant ('Agresso') project reference and /or a governance ('REDA') reference.

In this format:

(PI name)_(grant reference)_(governance reference)_(Agreement ID)_(Date or Version)

Or:

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Smith_12345-11_13.1234_MTARoche_01-01-12

The Agreement ID is selected by finding a descriptive identifier, usually incorporating the name of the other party.

The date or version is the date or version of the last alteration or signature.

Where no grant and/or governance reference exists, these can be omitted.

Other references such as EudraCT number should be quoted as required.

For CTIMPs sponsored by St. George's, the primary reference is the governance reference, and the Sponsor File should contain copies of all relevant agreements. A note should be made in the Sponsor File linking to other non-essential documentation as required.

7. References

ICH GCP

Management of amendments SOP - JREOSOP0011

Change management SOP - JREOSOP0029

8.Appendices

None associated with this SOP

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