

**SERVICE AGREEMENT**

**SPONSOR APPLICATION FOR SERVICES FOR A CLINICAL TRIAL OR OTHER RESEARCH STUDY**

*Instructions for completion, submission and use:*

* *Note: This Service Agreement is designed for the procurement of a service for a clinical trial or research study, without the Service Provider being a Site. It is designed for a Study only and not for on-going service provision.*
* *NSLHD will pay the Service Provider the services as set out in the attached Schedule (****Services****).*
* *The Service Provider agrees to perform the services set out in the attached Schedule.*
* *Please complete all sections highlighted yellow and submit pages 2 – 8 to the NSLHD Research Office for review, prior to obtaining signatures.* [*NSLHD-Research@health.nsw.gov.au*](mailto:NSLHD-Research@health.nsw.gov.au)
* *Once approved, the Research Office will return the draft for sign off from the service provider prior to resubmission to the Research Office via Regis for NSLHD sign off.*

**Schedule**

|  |  |
| --- | --- |
| Sponsor  (clause 1(a)) | Northern Sydney Local Health District, 63 834 171987  Executive Unit, Level 14, Kolling Building, Royal North Shore Hospital, Reserve Road, St Leonards NSW 2065 |
| Address of the CRG for notices and billing | Attention: [insert]  Address: [insert]  Fax: [insert]  Email: [insert] |
| Service Provider Name and ABN (clause 1(a)) | Name: [Insert]  ABN: [Insert] |
| Address of the Service Provider for notices and billing | Attention: [insert]  Address: [insert]  Fax: [insert]  Email: [insert] |
| Term (clause 1(c)) | Commencement Date: [insert]  End Date: [insert] |
| Study Name: | XX |
| Protocol No: - | XX |
| Name of HREC supervising the Study | XX |
| Name of Principal Investigator for CRG | XX |
| Services to be provided by the Service Provider(clause 2) | [insert] |
| Nominated Specialist (of the Service Provider) and required Qualifications | XX |
| Responsibilities of the CRG (if any) (clause 2(j)) | XX |
| Fees (inclusive of GST)  (clause 3) | Fees: [insert and describe in detail how the fee is payable, i.e. at completion in arrears, |
| Intellectual property (if not owned by CRG) | XX |
| Reporting and records (clause 14) | (What sort of reports are required, in what format and in what frequency – eg how do we establish the fees are spent appropriately and services being delivered?) |
| Disbursements (clause 3(d)) | [insert] |

1. Agreement and term
   * 1. This agreement is made between the sponsor named in the Schedule (**Us, We**) and the Service Provider named in the Schedule (**You**).
     2. We agree to purchase and You agree to provide the services identified in the Schedule (**Services**) subject to these terms and conditions.
     3. Subject to the terms and conditions of this Agreement, the rights and obligations of the parties will commence on the Commencement Date and will end on the End Date as specified in the Schedule (**Term**).
2. STUDY and Services
   * 1. You are responsible for the Services to be conducted in accordance with this Agreement.
     2. The parties acknowledge that they are not for profit organisations and the Study will be conducted in the spirit of cooperation and collaboration.
     3. In consideration of the payment of the Fee(s), You will provide to Us the Services in accordance with the Protocol, the timeframes, milestones and specification set out in the Schedule.
     4. You must ensure that all clinicians employed or contracted by You to provide the Services (including the Nominated Specialist named in the Schedule) have appropriate registration, qualifications and experience to provide the Services, including the Qualifications for the Nominated Specialist specified in the Schedule. You must provide to Us upon request documentation reasonably requested by Us to verify the Qualifications of those clinicians.
     5. You must advise Us as soon as possible if the Nominated Specialist fails to maintain the Qualifications during the term of this Agreement.
     6. In the event of any Nominated Specialist not maintaining the Qualifications, You must immediately withdraw the services of that person.
     7. You must maintain all necessary licences to provide the Services.
     8. You must provide the Services:
        1. with due care and skill and applying nationally accepted operating and management procedures;
        2. without unnecessary or unreasonable delays;
        3. in accordance with good clinical practice;
        4. in accordance with all applicable laws, authorisations, regulations and guidelines;
        5. the employment of adequate numbers of appropriately qualified, experienced and trained personnel;
        6. with sufficient resources;
        7. in a manner safe to workers, Study Participants and the public; and
        8. in accordance with the Protocol.
     9. We must provide the resources and material (if any) as set out in the Schedule.
3. Fee & disbursements
   * 1. In consideration of the provision of the Services, We must pay the Fees to You as specified in the Schedule.
     2. You will provide to Us tax invoices for payment of the Fees.
     3. We must pay our Fees within 14 business days of the tax invoice being received by Us.
     4. We must reimburse You for any out of pocket expenses incurred by You in the performance of the Services as specified in the Schedule.
4. GST
   * 1. All consideration provided under these Terms and Conditions is inclusive of GST, unless it is expressed to be GST exclusive.
5. Variations
   * 1. We may request You (in writing) to vary the Services provided the variation is within the general scope of the Services described in the Schedule.
     2. The variation, including any variation to the Fees must be:
        1. agreed by both parties; and
        2. in writing,

prior to the variation being implemented.

* + 1. Unless expressly varied pursuant to clause 5(b), the rights and obligations of the parties remain in force in accordance with this Agreement.

1. Confidentiality
   * 1. “Confidential Information” means confidential information of a party and includes information whether verbal, written or in some other form, including electronic form, relating to:
        1. knowledge or information regarding the business transactions, affairs, clients or suppliers property, policies, procedures or activities of a party;
        2. any document which is marked confidential; and
        3. any document or information which a party advises the other party is confidential.
     2. A party must not disclose to any person any Confidential Information of the other party for any purpose other than to perform its obligations under this Agreement, except as required by law, court order or any governmental or regulatory authority.
     3. This clause survives the expiration or termination of this Agreement.
2. privacy
   * 1. Each party must ensure that any Personal Information of Study participants or personnel of the other party it obtains or holds as a result of the conduct of the Study is collected, stored, used and disclosed by it in accordance with the relevant Privacy Laws.
     2. Each party will promptly report to the other party any unauthorised access to, use or disclosure of Personal Information of Study Participants ("Incident") of which it becomes aware, and will work with the other party to take reasonable steps to remedy the Incident.
     3. In this clause “Personal Information” has the same meaning as in the *Privacy and Personal Information Protection Act 1998 (NSW))*.
3. Intellectual Property Rights
   * 1. The following definitions apply in this clause:

**“Background IP”** means Background Intellectual Property of a party means information, techniques, know-how, software and materials (regardless of the form or medium in which they are disclosed or stored) that are provided by or on behalf of that party to the other for use in the Study or in relation to the Services (whether before or after the date of this Agreement) or used by that other party in conducting the Study and/or providing the Services, and all Intellectual Property in them, but excludes the Study Materials

**“Intellectual Property Rights”** means all present and future industrial and intellectual property rights, including without limitation:

* + - 1. inventions, patents, copyright, trade, business, company or domain names, rights in relation to circuit layouts, plant breeders rights, registered designs, registered and unregistered trade marks, know how, trade secrets and the right to have confidential information kept confidential, and any and all other rights to intellectual property which may subsist anywhere in the world; and
      2. any application for or right to apply for registration of any of those rights.

**“Study Materials”** means all materials and information created for the Study and/or in relation to the provision of the Services including all data, results, Biological Samples, reports in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Study and/or the Services which are discovered or developed as a result of the Study and/or the Services, but excluding Your ordinary patient records.

* + 1. We grant to You and your personnel the right to use Our Background IP and the Study Materials as required to carry out the Study, to perform the Services and perform this Agreement. Except for this right, neither You nor any of You personnel acquires any right or interest in any Intellectual Property Rights provided by or on behalf of Us.
    2. You grant to Us a non-exclusive, perpetual, royalty free licence to use (including the right to sub-licence) Your Background IP solely for the purpose of the non-commercialisation of the Study Materials.
    3. Subject to clause 8(c), all Intellectual Property in the Study Materials will vest automatically upon its creation in Us, and You assign to Us all existing and future Intellectual Property Rights (including all future copyright) contained in the Study Materials. You agree to execute or procure the execution by Your personnel of any documents reasonably necessary to give effect to this assignment, at Our expense.
    4. As a general principle, any Intellectual Property Rights specifically relating to any investigational product or equipment supplied by Us to You in relation to this Agreement shall be the sole property of the company owning the Investigational Product or Equipment. Nothing in this Agreement transfers any Intellectual Property rights (other than a right to use where expressly stated in this Agreement) in the equipment and the Investigational Product to You.
    5. You must not publish by way of a paper, article, manuscript, report, poster, internet posting, presentation, slides, abstract, outline, video, instruction material or other disclosure the Study Materials (except as required by Law) without Our prior written approval, which may be withheld in our absolute discretion.
    6. This clause 8 shall survive the expiry or termination of this Agreement.

1. Disputes
   * 1. Disputes shall as far as possible, be resolved by the parties undertaking negotiation in good faith.
     2. If the dispute is not resolved within a reasonable period of time, then the dispute is to be referred to the Australian Commercial Disputes Centre for mediation or any other agreed venue which conducts mediation.
     3. The parties will share in equal proportion the mediator’s fee. Each party shall pay their own costs of the mediation.
     4. A party may not commence any court or arbitration proceedings relating to a dispute unless it complies with this clause 9 except where the party seeks urgent interlocutory relief or this Agreement provides such a right.
2. liability and insurance
   * 1. Each party is liable for its acts and omissions in relation to the conduct of the Study.
     2. You will be responsible for your provision of the Services.
     3. Each party must maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the Study or performing its obligations under this Agreement.
     4. You must maintain:
        1. workers compensation insurance as required by law;
        2. public liability insurance in the amount of not less than $10 million in respect of each and every occurrence and in the aggregate for any one period of cover;
        3. professional indemnity insurance in the amount of not less than $10 million for any one occurrence and in the aggregate for any one period of cover.
     5. Upon request by Us, You must provide to Us certificates of insurance for the insurance referred to in clauses 10(c) and 10(d).
     6. A party satisfies the requirements of clauses 10(c) and 10(d) if it is entitled to indemnity under a program or scheme of insurance or indemnity that is arranged by a State or Territory of the Commonwealth of Australia.
     7. This clause 10 survives the expiry or termination of this Agreement.
3. Termination
   * 1. A party may terminate this Agreement at any time by providing to the other party 30 days’ notice of termination in writing.
     2. If We terminate this Agreement before the End Date, We must pay You for:
        1. all Services performed up to and including the date of termination; and
        2. all disbursements incurred by You up to the date of termination.
     3. If either party becomes insolvent or commits a breach of this Agreement (such breach, if capable of remedy, not being remedied within 14 days of written notice) the other party may terminate this Agreement by giving written notice to the other party to that effect.
     4. Upon termination, each party must return to the other party all confidential information supplied under this Agreement.
4. Subcontracting and assignment
   * 1. Neither party may assign, novate, transfer, subcontract or otherwise deal with its rights or obligations under this Agreement without the prior written consent of the other party, such consent not to be unreasonably withheld.
5. RECORDS AND REPORTING
   * 1. You must keep full and accurate accounts and records regarding the Services so that We can verify Your undertaking of the obligations under this agreement.
     2. You must keep record of all accounting and financial transactions in respect of the Fees.

### Required records must be kept in accordance with applicable Law and usual record keeping practices;

### You must provide to Us the reports at the times and in the format stated in the Schedule. In addition to any reports in the Schedule, You must provide the Agency with any information, records or reports in relation to the Services, the expenditure of the Fees or the obligations under the Agreement when requested to do so by Us.

1. General
   * 1. This Agreement constitutes the entire agreement between the parties and supersedes and extinguishes all previous drafts, agreements, arrangements and understandings, whether written or oral, relating to its subject matter.
     2. No variation of this Agreement will be of any force or effect unless it is in writing and signed by the parties.
     3. Nothing in this Agreement will constitute or be construed to constitute a party as the partner, agent, employee or representative of any other party or to create any trust relationship between them.
     4. A party will not be responsible for events outside its reasonable control.
     5. This Agreement is governed by the law of New South Wales. The parties submit to the non-exclusive jurisdiction of its courts and courts of appeal from them.

**Executed** as an agreement

Signed for and on behalf of **Northern Sydney Local Health District**, Executive Unit, Level 14, Kolling Building, Royal North Shore Hospital, Reserve Road, St Leonards NSW 2065, by its duly authorised officer:

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*Signature of Authorised Officer*

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*Name of Authorised Officer*

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*Position of Authorised Officer*

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*Date*

**Signed** for and on behalf of **[Recipient]** by its duly authorised officer:

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*Signature of Authorised Officer*

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*Name of Authorised Officer*

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*Position of Authorised Officer*

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*Date*