**<INSERT NAME OF ADMINISTERING INSTITUTION>**

**MULTI-INSTITUTIONAL AGREEMENT**

**for**

**NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL (NHMRC)**

**CLINICAL TRIALS AND COHORT STUDIES Grant**

**WHERE research activities include a clinical trial**

*[Note: Where there is more than one clinical trial/study/protocol this template could be modified, including there being more than one Sponsor so long as there is only one Sponsor for each clinical trial.]*

**DETAILS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **NHMRC ID:** | | **APP <Insert NHMRC ID>** | **First Funding Year** | | **2021** |
| **Scheme:** | | **NHMRC Clinical Trials and Cohort Studies Grant** | | | |
| **Project Title:** | | **<Insert Project Title>** | | | |
| **Funding Period:** | | **<insert number of years> Years** | | | |
| **Funds Awarded:** | | **<Insert total amount funded>** | | | |
| **Administering Institution and its first-named Chief Investigator (CI):** | | **Institution: <Insert Institution>** | **CI: <Lead CI>** | | |
| **Sponsor of the Study** | | *[Insert name of Administering Institution or Participating Institution to act as Sponsor of the Study or other party to be subcontracted as Sponsor of the Study. If the Sponsor of the Study is not a party to this Agreement, add “[Insert name of Party] will be responsible for subcontracting with the Sponsor of the Study.”]*  *[Where there is no Study, i.e. the Project is a cohort study only and does not include any clinical trial, state “Not applicable as the Project does not include a Study/Clinical Trial and therefore all references to Sponsor of the Study, Study, Clinical Trial, Protocol and Study Materials do not apply”.]* | | | |
| **Participating Institutions and their first-named Chief Investigator (Specified Personnel):** | | | | | |
| **Institution** | **Chief Investigator (CI)** | | | **Email address** | |
| **<Insert Institution>** | **<Insert CI>** | | |  | |
|  |  | | |  | |

**BACKGROUND**

1. The National Health and Medical Research Council (“NHMRC”) recognises the importance of fundamental research to the national innovation system and supports research undertaken by individual researchers or research teams through its various Schemes.
2. The Administering Institution, with the support and assistance of the Participating Institutions, successfully applied for Funds under the NHMRC Funding Scheme.
3. The NHMRC requires that an Administering Institution must not allow a Participating Institution to commence performing any part of a Research Activity nor provide Funding to that Participating Institution, until it has entered into a Formal Agreement, in respect of the Project, with each Participating Institution in accordance with the NHMRC Funding Agreement.
4. The Administering Institution and the Participating Institution(s) agree that the management and performance of the Project will at all times be in accordance with the NHMRC Funding Agreement and the NHMRC Funding Policy.
5. The Study has been developed collaboratively and each Party has had an opportunity to exercise its own judgement, skills and expertise in assessing the Study including the Protocol and all associated risks.

*[Note: Recital E could be deleted where this does not apply eg if the Study has not yet been developed and/or only some Participating Institutions are involved in the Study.]*

**THE PARTIES AGREE:**

1. DEFINITIONS
   1. In this Agreement, capitalised terms have the same meaning as set out in the NHMRC Funding Agreement unless otherwise defined in clause 1.2, and unless the contrary intention appears, the interpretation provisions of the Funding Agreement apply to the interpretation of this Agreement:
   2. In this Agreement:

**Agreement** means this agreement once it is executed by all the Parties, including the schedules and any attachment and/or annexures which may be incorporated into this Agreement by reference, as may be amended from time to time in accordance with its terms.

**Biological Samples** means any physical samples obtained from Study Participants in accordance with the Protocol for the purposes of the Study.

**Case Report Form** means a printed, optical or electronic document or database designed to record all of the information which is required by the Protocol to be reported on each Study Participant.

**Clinical Trial** means any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

**Cohort studies** are observational studies in which a study population (a cohort) is followed over time to evaluate the impact of an exposure (or intervention) on health or other outcomes**.**

**EU Data Protection Legislation** means the General Data Protection Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of Personal Data (as defined in the General Data Protection Regulation (EU) 2016/679) and on the free movement of such data, and repealing Directive 95/46/EC and all other applicable laws and regulations relating to or impacting the processing of such data.

**Grant Guidelines** means the NHMRC Clinical Trials and Cohort Studies Grants 2019 Guidelines. The Grant Guidelines can be accessed at <https://www.grants.gov.au/?FOUUID=44D91467-AB43-9F84-B95BDFB84E8CAA27&event=public.FO.show>.

**Institution** means the hospital or clinic at or having control of the Study Site**.**

**Material means** includes any material, documentation, information, data, results, samples (including Biological Samples), reports in whatever form held, and any conclusions, discoveries, inventions, know-how and the like, whether patentable or not**.**

**Medicines Australia CTRA** means the current version of the Medicines Australia Clinical Trial Research Agreement - Collaborative or Cooperative Research Group (CRG) Studies – Standard Form. The Medicines Australia CTRA can be accessed at <https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements>.

**MTAA CTRA** means the Medical Technology Association of Australia standard terms and conditions for clinical trial investigation research agreements available at <https://www.mtaa.org.au/clinical-investigations>**.**

**NHMRC Funding Agreement** means the agreement between the Commonwealth (as represented by the NHMRC) and the Administering Institution regarding Funding for Research Activities to commence in the First Funding Year, as amended from time to time. The NHMRC Funding Agreement can be accessed at https://www.nhmrc.gov.au/funding/manage-your-funding/funding-agreement-and-deeds-agreement.

**Party** means a party to this Agreement and **Parties** means all of the parties to this Agreement.

**Project** means the project named in the Details and more specifically detailed in the Application.

**Project Contributions** means the cash and/or in-kind contributions from each Party, including any relevant third party contribution, to the Project as specified in Schedule 4 or as otherwise agreed between the Parties in writing and approved by the NHMRC (if required).

**Project Intellectual Property** (Project IP)means any Intellectual Property and Material created or arising as a direct result of the conduct of the Project, including Research Material **but excluding Study Materials.**

**Protocol** means the document which describes the objectives, design, methodology, statistical considerations and organisation of the Study, as such document may be amended from time to time and most recently approved by the Responsible HREC.

**Regulatory Authority** or Regulatory Authorities means any body which has jurisdiction over the conduct of the Study at the Study Site and includes the Therapeutic Goods Administration, and any overseas regulatory authorities who may audit or require to be audited, any part of the Study or Study Materials.

**Responsible HREC** means the Human Research Ethics Committee(s) reviewing the Study on behalf of the Institution(s).

**Specified Personnel** means, in respect of a Party, the persons named as Chief Investigators in the ‘Details’ section of this Agreement, and such other persons as may be approved by the NHMRC in accordance with the NHMRC Funding Agreement to perform all or part of the Project from time to time.

**Sponsor** has the meaning set out in clause 1.53 of the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) as adopted by the Therapeutic Goods Administration*. The Sponsor of the Study is identified in the Details.

**Student** means a student of any of the Parties who has been approved by the other Parties’ Chief Investigator(s) to participate in the Project.

**Study** means that part of the Project to be conducted in accordance with the Protocol, which has been determined to be a Clinical Trial.

**Study Materials** means all the Materials and information created or arising in the course of the conduct of the Study and includes all data, results, Biological Samples, Case Report Forms (or their equivalent) in whatever form held, and conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Study which are discovered or developed as a result of the Study.

**Study Participant** means a person recruited to participate in the Study.

**Study Sites** means the location(s) where under the control of the Instituttion where the Study is actually conducted.

* 1. If there is any inconsistency between:

1. the NHMRC Funding Agreement;
2. this Agreement; and
3. any schedule, attachment or annexure,

the documents will prevail in the order listed from (a) to (c) above.

1. **CONDUCT OF THE PROJECT**
   1. The Parties agree:
2. that they have each received a copy of the Application and agree that the roles, budget, contributions and program of research of each of the Parties in relation to the Project are set out accurately in the Application and this Agreement;
3. to each carry out their roles, responsibilities and program of research and provide their Project Contributions as set out in this Agreement and in the Application or as varied from time to time with the prior approval of the Parties and the NHMRC (if required);
4. to act in a manner that is consistent with, and enables the Administering Institution to give effect to, all of the Administering Institution’s obligations under the NHMRC Agreement;
5. to conduct the Project in accordance with the NHMRC Approved Standards, Guidelines and any applicable NHMRC policies (including obtaining, maintaining and complying with any Institutional Approvals);
6. to carry out the Project in an ethical, responsible, diligent and competent manner;
7. to ensure that the Project is performed and completed within the Funding Period unless otherwise varied by the NHMRC in accordance with the NHMRC Funding Agreement;
8. to ensure that their Specified Personnel perform the Project in accordance with the Application and this Agreement;
9. to implement sound research governance procedures in respect of the Project, including cooperation in complying with the procedures for notification of Misconduct and notification and management of breaches or potential breaches of the *Australian Code for the Responsible Conduct of Research* (2018) in accordance with the NHMRC’s Integrity Policy, and associated *Guide to Managing and Investigating Breaches of the Australian Code for the Responsible Conduct of Research* (2018), as amended from time to time;
10. to cooperate with each other in relation to any complaints or allegations about potential breaches of the *Australian Code for the Responsible Conduct of Research* (2018), including Research Misconduct;
11. that any Institutional Approval, including statements of compliance and/or ethics clearance necessary for the performance of a Research Activity where applicable must be obtained prior to the commencement of that Research Activity and any associated Funding must not be expended until Institutional Approvals have been granted;
12. to comply with the requirements of the Australian Privacy Principles under the *Privacy* *Act 1988* (Cth) and such other relevant laws or regulations prevailing in the jurisdiction in which the Study is being undertaken or in which the Administering Institution or a Participating Institution is located in relation to the use, collection, storage and security or disclosure of any personal and/or health information collected or used during the Project, and the *Guidelines approved under Section 95A of the Privacy Act 1988 (2014)* and the *Guidelines under Section 95 of the Privacy Act 1988 (2014)*;
13. to the extent that any Party is a Data Controller and another Party or Parties are a Data Processor (as those terms are defined under the EU Data Protection Legislation) in carrying out their roles, responsibilities and program of research under this Agreement, the Parties shall comply with all applicable requirements of the EU Data Protection;
14. not to use any form of child labour, bonded labour, forced labour nor other forms of slavery or slavery-like conditions or human trafficking, and to abide by all other obligations under any applicable anti-slavery legislation;
15. to maintain appropriate records of their involvement in the Project in accordance with clause 8 of the NHMRC Funding Agreement;
16. to cooperate with each other in providing information that the Administering Institution requires to compile the Reports required under clause 9 of the NHMRC Funding Agreement in relation to the Project;
17. to provide the Commonwealth with access specified in clause 11 of the NHMRC Funding Agreement;
18. that any Assets purchased with the Funds will be dealt with in accordance with clause 13 of the NHMRC Funding Agreement;
19. to use the NHMRC logo and acknowledge the Funding consistently with the requirements of clause 20 of the NHMRC Funding Agreement;
20. that the NHMRC is entitled to use information relating to the Project in accordance with clause 21 of the NHMRC Funding Agreement;
21. to notify the Administering Institution if any of the circumstances set out in clause 31.4 of the NHMRC Funding Agreement arises; and
22. to comply with any applicable statutes, regulations, by-laws and requirements of the Commonwealth and any State, Territory or local authority.
    1. Each Party agrees to:
23. carry out its role in the Study (and ensure that any third parties it engages to undertake the Study agree to carry out their roles in the Study) in accordance with:
    1. the Protocol;
    2. any relevant Commonwealth and State or Territory laws and any requirements of Regulatory Authorities;
    3. the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)* as adopted by the Therapeutic Goods Administration;
    4. the *NHMRC National Statement on Ethical Conduct in Human Research (2007) – updated 2018* or its replacement, and any other relevant NHMRC publication or guideline that relates to human research;
    5. the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 1996 (as accepted by the Australian Government); and
    6. any reasonable direction given by the Sponsor of the Study, where the Party is not the Sponsor, in order to ensure the safe conduct of the Study and compliance with applicable regulatory requirements, including any condition of a Responsible HREC;
24. ensure that any personal information arising from the Study regarding Study Participants or the personnel involved in the Study is collected, stored, used and disclosed in accordance with the Privacy Act 1988 (Cth) and any other legislation, code or guideline which applies to the Party and relates to the protection of personal information;
25. keep all Biological Samples which are the subject or outcome of the Study in appropriate storage conditions in areas accessible only to authorised personnel; maintain complete and current records (including data and reports) in relation to its performance of the Study;
26. that it will not involve in the Project any of its personnel (including any personnel of its subcontractors) who have been found to have engaged in Misconduct related to NHMRC Funding within the last 3 years; and
27. ensure that records are retained and preserved for at least 15 years from completion of the Project.
    1. The Party which is the Sponsor of the Study agrees to (or, where the Sponsor of the Study is not a Party, the Party which takes responsibility for entering into an agreement with the Sponsor of the Study will ensure that the Sponsor of the Study agrees to):
       1. ensure that the Study is registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) or equivalent before recruitment of the first Study Participant; and
       2. enter into an agreement with each Study Site which, in the case of medicines, would be substantially in the terms of the Medicines Australia Clinical Trial Research Agreement - Collaborative or Cooperative Research Group (CRG) Studies – Standard Form (Medicines Australia CTRA) or, in the case of medical devices or software as a medical device, would be substantially in the terms of the MTAA CTRA [, including the Schedule 4 Special Terms for clinical trials funded under the NHMRC Funding Agreement, which have been approved for the University of Sydney by the Southern and Eastern Border States (SEBS) - Queensland, New South Wales, Victoria and South Australia, which are attached as Annexure 1 of this Agreement, or in the case of medical devices or software as a medical device will be substantially in the terms of the equivalent MTAA CTRA terms].
    2. Each Party agrees that, if any issue relating to the safety of Study Participants arises which requires a deviation from the Protocol, the Sponsor may immediately make such a deviation without breaching any obligations under this Agreement. If there is a need for such a deviation the Sponsor must notify the other Party/Parties and the Reviewing HREC of the facts and circumstance giving rise to the requirement for the deviation as soon as is reasonably practical, but in any event no later than 5 working days after the deviation is implemented.
    3. Each Party agrees that it is liable for its acts and omissions in relation to the conduct of the Study and must maintain such insurance policies as are reasonably available and necessary to provide indemnity to that Party in relation to any liability which it may incur in conducting the Study or performing its obligations under this Agreement.
    4. In carrying out the Project and using and managing the Funds, each Participating Institution agrees:
28. to, and ensure that its Specified Personnel, abide by the terms and conditions of the NHMRC Funding Agreement, the NHMRC Funding Policy and any Funding Conditions that apply to the Project, and all applicable NHMRC Approved Standards and Guidelines (including the Grant Guidelines, and obtaining, maintaining and complying with any Institutional Approvals) to the extent that they relate to Participating Institutions;
29. to provide reasonably requested assistance to the Administering Institution for the purposes of enabling the Administering Institution to report to the NHMRC against milestones and performance indicators as required under section 12.2.4 of the Grant Guidelines;
30. not to in any way impede or prevent the Administering Institution from complying with any of its obligations under the NHMRC Funding Agreement; and
31. to do all things reasonably required to assist the Administering Institution to meet its obligations under the NHMRC Funding Agreement including reporting, compliance and financial management obligations relating to the Funding and,
32. to require any subcontractor to comply with the applicable obligations of the Participating Institution under this Agreement and, where the subcontractor contributes to or creates Project outputs, to enter into a written subcontract with that subcontractor on terms consistent with this Agreement, including Intellectual Property obligations and, where applicable, EU Data Protection Legislation obligations.
33. **PROJECT FUNDING**
    1. Subject to the NHMRC providing the Funding to the Administering Institution under the NHMRC Funding Agreement, the Administering Institution will retain, and distribute to the Participating Institution(s), the Funding in accordance with Table 1 below. All references to dollars in this Agreement are to Australian dollars and Funding will be paid in Australian dollars.

**Table 1: Distribution of Funding**

*[Note: This reflects funding from the Administering Institution to the Participating Institutions as collaborators on the Project. Organisations providing only services, including only acting as a site for the clinical trial, should not be included as a party to the agreement.]*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Institution Name** | **2021** | **2021** | **2022** | **2023** | **2025** | **TOTAL** |
| <Insert Administering Institution name> | **$** | **$** | **$** | **$** | **$** | **$** |
| <Insert Participating Institution name> | **$** | **$** | **$** | **$** | **$** | **$** |
| <Insert Participating Institution name> | **$** | **$** | **$** | **$** | **$** | **$** |
|  |  |  |  |  |  |  |
| Total NHMRC Grant (indicative only) | **$Total** | **$ Total** | **$ Total** | **$ Total** | **$ Total** | **$ Total** |

A party (other than an Australian University) conducting the Study or undertaking other work in respect of the Project does so as a service provider.

* 1. The Parties agree that Funding will be spent only on the Project and in accordance with the budget approved under the Application unless otherwise agreed in writing between the Parties and approved by the NHMRC (if required).
  2. Where the Administering Institution distributes Funding to a Participating Institution, that Participating Institution will:

1. submit relevant invoices to the Administering Institution on a quarterly basis, in arrears, from the commencement of the Funding Period, which for Participating Institutions in Australia shall be tax invoices;
2. provide an annual financial acquittal to the Administering Institution by 28 February of each year for the Funding distributed to the Participating Institution in the previous calendar year;
3. deal with the Funding received from the Administering Institution in the same way as the Administering Institution is required to deal with the Funding under clause 7 of the NHMRC Funding Agreement except that the Participating Institution is required to provide information to, and seek approval from, the Administering Institution rather than the NHMRC;
4. repay to the Administering Institution any Funds provided by the Administering Institution to the Participating Institution for the Research Activity that the Participating Institution has not spent on the Research Activity in accordance with this Agreement; and
5. if any Specified Personnel leave the employment of the Participating Institution through a transfer to another university or otherwise, and the involvement of the Participating Institution in the Project ceases as a result, the Participating Institution will provide a Transfer Acquittal Statement within 20 days as required by the Administering Institution in accordance with clause 9.8 of the NHMRC Funding Agreement.
   1. The contact details for invoices at the Administering Institution and acquittals for any relevant Participating Institution(s) are provided at Schedule 3.
   2. All amounts referred to in this Agreement are expressed exclusive of GST unless otherwise stated. For the purpose of this agreement, “GST” means a goods and services tax imposed on the supply of goods and services (including intellectual property) under A New Tax System (Goods and Services Tax) Act 1999 (Cth) (as amended from time to time). The Administering Institution will, on issue of a complying tax invoice, pay the Participating Institution(s) an amount equal to the GST liability payable by the Participating Institution(s).
6. **INTELLECTUAL PROPERTY**
   1. The Parties agree that the ownership of Existing Material and Commonwealth Material is not affected by this Agreement and that all Existing Material remains the property of the Party that makes it available for the purpose of carrying out the Project and all Commonwealth Material remains the property of the Commonwealth. All improvements to Existing Material will upon its creation vest in the party that owns such Existing Material.
   2. Each Party grants to each other Party a royalty-free, non-exclusive, non-transferrable licence to use its Existing Material to the extent necessary to carry out the Project. Each Party agrees to comply with any reasonable directions of another Party regarding the use of that other Party’s Existing Material.
   3. The Participating Institution(s) grant or will procure the grant of a permanent, irrevocable, free, world-wide, non-exclusive licence (including the right to sub-licence) to the Administering Institution in respect of the relevant Existing Material to satisfy clause 12.5 of the NHMRC Funding Agreement but for no other purpose.
   4. No representations or warranties are made or given in relation to Existing Material, however each Party making available Existing Material acknowledges that to the best of its knowledge, such Existing Material when used in accordance with this Agreement will not infringe any third party Intellectual Property rights.
   5. Subject to clause 4.6, the Parties agree that all rights, title and interest in the Project Intellectual Property (except for copyright in a Student thesis) will be owned solely by the Party, or jointly by the Parties, that contribute to its development or creation, and that the Study Materials will be owned by the Sponsor of the Study, who will ensure that Intellectual Property in Study Materials developed or created at Study Sites is assigned by the Institution to the Sponsor of the Study. In the case of jointly owned Project Intellectual Property, the relevant Parties will own the Project Intellectual Property as tenants in common in shares proportionate to their respective intellectual contributions to the development or creation of that Intellectual Property.
   6. The Parties agree that copyright in a Student thesis will be owned by the Student but the Party where the Student is enrolled will ensure that the Student enters into written arrangements which are consistent with and enable that Party to give effect to the terms of clause 4 of this Agreement before the Student commences any Research Activities on the Project.
   7. The administration and management of the Project IP will comply with the *National Principles of Intellectual Property Management for Publicly Funded Research*.
   8. All Parties are committed to appropriate recognition of contributions to invention and exploitation of Intellectual Property for the benefit of the Australian community.
   9. The Parties each agree to ensure that their respective staff and Students working on the Project promptly provide to the Administering Institution written notice (within a reasonable time) of any Project IP that may have potential commercial value if and when such staff and Students become aware of such Project IP.
   10. The Parties who own Project Intellectual Property (as determined in accordance with clause 4.5) will consult and decide what (if any) measures should be taken to protect the Project IP and negotiate in good faith and using all best endeavours to agree the terms of any program of commercialisation arising from the Project IP so as to make fair and equitable arrangements to meet any costs associated with the protection and registration of the Project IP and to share in any commercial return associated with the Project and the Project IP. The parties will also negotiate in good faith in respect of any licences for Existing Material to the extent and where use of the Project IP is reliant on such Existing Material.
   11. Having regard to any requirements to protect potentially commercially valuable Project IP and Intellectual Property in Study Materials and the rights of the Parties in their Existing Material, each Party grants to each other Party a non-exclusive, non-transferable, perpetual, royalty free, worldwide licence to use the Project IP and Intellectual Property in Study Materials they own for during and after the completion of the Project for:
       1. non-commercial research, education and training purposes; and
       2. publication purposes (subject to clause 6 of this Agreement).
   12. The Participating Institution(s) grant or will procure the grant of a permanent, irrevocable, free, world-wide, non-exclusive licence (including the right to sub-license) to the Administering Institution to use, reproduce, communicate, modify and adapt any Project IP and Intellectual Property in Study Materials they own which is included in Research Material or Incorporated Material to satisfy clauses 9 and 12.5 of the NHMRC Funding Agreement but for no other purpose.
   13. The Parties will use their best endeavours to arrange for each of their authors of Research Material or Incorporated Material to provide written consent to the Specified Acts as may be required by the NHMRC in accordance with clauses 12.6, 12.7 and 12.8 of the NHMRC Funding Agreement.
7. **SUPPLY AND USE OF BIOLOGICAL SAMPLES**
   1. During the Project a Party (Supplying Party) may transfer Biological Samples to another Party (Recipient Party) to enable the Recipient Party to use those Biological Samples for the purposes of the Project during the Term.
   2. The Recipient Party:
      1. must handle and use the Biological Samples in compliance with all applicable legislation, regulations, codes and guidelines;
      2. must not use the Biological Samples in any human body fluids, extracts of human tissues, human tissue in explant culture or human cells in cell culture, without the prior written consent of the Supplying Party and the Administering Institution;
      3. must use its best efforts to ensure that its employees, students, agents, contractors and officers use the Biological Samples only in accordance with the terms of this Agreement and the relevant human subject consent;
      4. acknowledges that the Biological Samples are experimental in nature and may have defects, deficiencies and hazardous properties;
      5. must, at the expiration or termination of this Agreement, at its own cost, return, transfer or dispose of all remaining Biological Samples as instructed by the Administering Institution.
   3. To the extent permitted by law, all conditions, warranties, guarantees, rights, remedies, liabilities or other terms that may be implied or conferred by statute, custom or the general law that impose any liability or obligation on the Supplying Party or the Administering Institution in relation to the Biological Samples are expressly excluded under this Agreement.
8. **PUBLICATIONS** 
   1. Subject to clause 7.1 each Participating Institution agrees to provide the Administering Institution with any publications resulting from a Research Activity and its related data in order for the Administering Institution to comply with the obligations under clauses 12.9 and 12.10 of the NHMRC Funding Agreement in relation to the dissemination of research findings as required by the Funding Policy or another NHMRC policy.
   2. The Parties are entitled to publish the results of the Project subject to clause 6.4.
   3. The Parties acknowledge that a Student may include the results of the Project in whole or in part in the Student’s thesis, in which case the non-enrolling institution(s) whose Confidential Information and/or Intellectual Property will be prejudiced if it is published in the Student’s thesis may reasonably request that the thesis be submitted to examiners in confidence and that the thesis be held in restricted confidential storage in accordance with the enrolling institution’s applicable regulations, by-laws and procedures. Each party will endeavour to keep any period of restriction for a PhD thesis to a minimum.
   4. The publishing Party will provide a copy of the proposed publication to each other Party at least 28 days in advance of submitting for publication. The other Parties may provide comments and/or reasonable amendments to the publication to protect their Confidential Information and/or Intellectual Property, including requesting removal or delay to the inclusion of information which may pre-empt the other Party’s publication of its Project IP which is not jointly owned with the publishing Party, provided the comments and/or amendments are given to the publishing Party in writing no later than 14 days before the publication is proposed to be submitted. If no such comments or amendments are provided within the 14 day period, the publishing Party can submit the proposed publication, subject to any applicable requirements under the NHMRC Funding Agreement. Where a Party requests that the material be amended, the publishing Party will use all reasonable efforts to amend the proposed publication accordingly and, if requested, delay submission of the publication for a period not exceeding 6 months to allow appropriate registration of any registrable Intellectual Property.
   5. Notwithstanding this clause 6, the Parties agree that a Party may not publish any Study Material without the prior written consent of the Sponsor of the Study (not to be unreasonably withheld) and if a publishing Party does not receive a response to a request to publish from the Sponsor of the Study within 14 days of the request, consent is deemed granted.
9. **CONFIDENTIALITY**
   1. Each Party acknowledges that all Confidential Information disclosed by one Party to the other, whether existing prior to the commencement of the Project or created in the course of the Project, will be kept confidential and shall not be disclosed to any third party without the prior written consent of the disclosing party, such consent not to be unreasonably withheld or delayed.
   2. Notwithstanding clause 7.1, the Administering Institution may disclose Confidential Information, including the terms of this Agreement, where permitted by applicable law, if required by the NHMRC under the terms of the NHMRC Funding Agreement and the Parties may disclose Confidential Information to their employees, contractors and Students involved in the Project, or their related entities, on a need to know basis as may be necessary for the purposes of this Agreement provided that each such recipient is made aware of the confidential nature of the information and bound to keep the information in confidence. Each Party may disclose its Confidential Information and any other Party’s Confidential Information if required by law, including a request under Freedom of Information legislation, but, if possible, it must inform the relevant other Parties first and use reasonable endeavours to limit the terms of that disclosure as reasonably requested.
   3. The Parties acknowledge the obligations of each other Party under their respective statutes to deposit in the library a copy of a Student’s completed thesis or work submitted for a higher degree. Nothing in this Agreement affects the operation of those statutes or creates any obligations contrary to those statutes.
10. **CONFLICT OF INTEREST**
    1. The Parties warrant that to the best of their knowledge, as at the date of this Agreement, there is no Conflict of Interest which will affect their Specified Personnel’s conduct of the Research Activity, or their Specified Personnel’s contribution to any committees established in relation to this Project, including in relation to the activities undertaken by other Specified Personnel.
    2. If a Party becomes aware of a Conflict of Interest during the term of this Agreement, that Party will notify the Administering Institution immediately, who will notify the NHMRC in writing of the full details of that Conflict of Interest if required and the steps the Administering Institution proposes to resolve or otherwise deal with the Conflict of Interest. The Parties agree to cooperate with each other to comply with any steps reasonably required by the NHMRC to resolve or otherwise deal with that Conflict of Interest under clause 29 of the NHMRC Funding Agreement.
11. **TERMINATION AND REDUCTION**
    1. The Administering Institution may terminate this Agreement if:
12. the NHMRC ceases to provide Funding for the Project or the NHMRC Funding Agreement is terminated for any reason, in which case the Administering Institution will notify the Participating Institutions and the Parties will meet to discuss available options regarding the Project and this Agreement; or
13. a Participating Institution breaches a material term of this Agreement and such breach is not remedied within 30 days of written notice of the breach by the Administering Institution to the Participating Institution.
    1. This Agreement may be terminated:
14. at any time by the Parties mutual written agreement; or
15. if the Project is wholly terminated.
    1. If the Administering Institution receives notice that a Participating Institution wishes to withdraw its involvement in the Project the Administering Institution will seek, in accordance with the NHMRC Funding Agreement, the remaining Parties consent to terminate this Agreement, or continue the Project with the remaining Participating Institutions. Where the Parties elect to proceed with the Project they will do all things necessary to amend this Agreement to reflect the new arrangements.
    2. If the NHMRC reduces the scope of the NHMRC Funding Agreement, the Project or the Funding, the Administering Institution will notify the Participating Institutions in writing and the Parties agree that this Agreement will be similarly reduced.
    3. Upon termination or reduction, the Parties will stop or reduce performance of the Project, take all reasonable steps to minimise loss resulting from the termination or reduction, continue to perform any Project obligations which are not affected by the reduction, and each Participating Institution will reasonably assist the Administering Institution to comply with a request from the NHMRC for the Funding to be repaid if that request arises from the Participating Institution’s conduct. The Parties will also return all Confidential Information and property belonging to the other Parties within 14 days of the termination date.
    4. No Party will be liable to the other upon termination of this Agreement for any compensation for loss of prospective opportunities or benefits that would have been conferred on another Party but for the termination or reduction in scope of this Agreement.
16. **INDEMNITY AND INSURANCE**
    1. Each Participating Institution indemnifies (and agrees to keep indemnified) the Administering Institution and the Administering Institution’s personnel (“those indemnified”) from and against any:
17. cost or liability incurred by those indemnified;
18. loss of or damage to property of those indemnified;
19. loss or expense incurred by those indemnified in dealing with any claim against them, including legal costs and expenses on a solicitor/own client basis and the cost of time spent, resources used, or disbursement paid by those indemnified;

arising from any claim that the NHMRC makes against the Administering Institution under clause 18 of the NHMRC Funding Agreement to the extent such loss or damage was contributed to by the Participating Institution.

* 1. The Participating Institutions liability to indemnify those indemnified under this clause 10 will reduce proportionately to the extent that any act or omission involving fault on the part of those indemnified contributed to the relevant, liability, loss or damage or loss or expense.
  2. The right of those indemnified to be indemnified under this clause 10 is in addition to and not exclusive of, any other right, power or remedy provided by law, but those indemnified are not entitled to be compensated in excess of the amount of the relevant cost, liability, loss, damage or expense.
  3. The Parties will have the equivalent insurance required of the Administering Institution under clause 19 of the NHMRC Funding Agreement.

1. **GENERAL**
   1. This Agreement commences on the date it is executed by the last Party and remains in force for the duration of the Funding Period (including any period of carry forward as approved by the NHMRC), unless otherwise agreed in writing between the Parties and approved by the NHMRC (if required).
   2. The Parties agree that the payments of salaries for Personnel, where applicable, will be made in accordance with the NHMRC Funding Agreement and the relevant employing institution’s human resources policy.
   3. If any dispute or difference arises in connection with this Agreement, then the Parties shall negotiate in good faith using their best endeavours to resolve the dispute or difference. If the dispute or difference cannot be resolved in the first instance, the Parties agree to refer the dispute to, as applicable, the Deputy Vice-Chancellors (Research) or Chief Executive Officers, or equivalent, or their nominees, with due regard to circumstances where the dispute or difference directly involves Specified Personnel who also fill the role of persons to whom the dispute or difference might otherwise be referred, in which case a more senior decision-maker should be identified.. In doing so, the Parties will comply with the procedure set out in clause 30 of the NHMRC Funding Agreement. Notwithstanding a dispute or difference, the Parties will continue to perform their obligations under this Agreement which are not affected by the dispute or difference.
   4. This Agreement may be signed in any number of counterparts which together will constitute one agreement.
   5. Each Party may communicate its execution of this Agreement by successfully transmitting an executed copy of this Agreement by facsimile or email to the other Party.
   6. If any clause (or part thereof) of this Agreement is held by a court to be invalid or unenforceable such clause or part thereof shall be deemed deleted from this Agreement and this Agreement shall otherwise remain in full force and effect.
   7. No addition to or modification of any provision of this Agreement shall be binding upon the Parties unless by written instruction signed by each of the Parties.
   8. Any failure by a Party to compel performance by the other Party of any of the terms and conditions of this Agreement will not constitute a waiver of those terms or conditions or diminish the rights arising from their breach.
   9. This Agreement shall be governed by and construed in accordance with the laws for the time being in force in the State or Territory of the Administering Institution and the Parties agree to submit to the jurisdiction of the courts of that State or Territory.
   10. If a right, duty or an obligation or liability under this Agreement applies to more than one Party then each such Party is entitled to the right or liability severally and not jointly, nor jointly and severally in respect of that right, duty, obligation or liability.
   11. This Agreement does not create a partnership, agency, fiduciary or other relationship between the Parties and no Party is liable for the acts or omissions of any other Party except as set out in this Agreement.
   12. This Agreement:

### contains the entire agreement of the Parties; and

### supersedes all prior representations, conduct and agreements,

with respect to its subject matter, except to the extent that any express guarantees have been given by a party as contemplated by section 59 of the Competition and Consumer Act 2010 (Cth).

* 1. If any applicable legislation prohibits the limitation or exclusion of liability by a Party in the manner contemplated by this Agreement with respect to particular loss or damage, then:

### the relevant limitation or exclusion does not apply to that loss or damage; and

### that Party’s liability is only limited or excluded with respect to that loss or damage in the manner permitted under that legislation (if any).

* 1. Subject to clauses 10.1 and 10.4 each party is not liable to the other parties in connection with this Agreement for any loss or damage however caused (including due to the negligence of that party) that is consequential loss, indirect loss, loss of profits, loss of revenue, loss of reputation, loss of bargain or loss of opportunity.

1. **SURVIVAL**
   1. The following clauses of this Agreement will survive the expiration or earlier termination of this Agreement: 1, 2.1 (i), 2.1(k), 2.1(l), 2.1(n), 2.1 (o), 2.1(p), 2.1(q), 2.1(r), 2.1(s), 2.2, 3.3, 4, 6, 7, 9.5, 9.6, 10, 11.3, 11.6, 11.8, 11.9, 11.10, 11.11 and 13, along with any other provision which by its nature survives termination or expiration of this Agreement.
2. **NOTICES**
   1. Any notice, request or other communication to be given or served pursuant to this Agreement shall be in writing and addressed to the other Party at the address as set out in Schedule 3 or such other address as a Party may notify the other Party from time to time.
   2. A notice, request or other communication will be deemed to be received:
      1. if delivered by hand, upon delivery;
      2. if sent by pre-paid ordinary post within Australia, upon the expiration of five (5) Working Days after the date on which it was sent; or
      3. if transmitted electronically, upon receipt by the sender of an acknowledgment that the communication has been properly transmitted to the recipient.

**Agreed to by the following Parties:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Institution** | **Name of First-named Chief Investigator on the Application** | **Name and Signature of Authorised Signatory**  **(DVC (Research) or authorised delegate of the Institution)** | **Date of signing by Authorised Signatory** |
| **<Insert name of Participating Institution>** | **< CI Name>** |  |  |
| **<Insert name of Participating Institution>** | **< CI Name>** |  |  |

**SCHEDULE 1 – NHMRC CLINICAL TRIALS AND COHORT STUDIES GRANT APPLICATION**

Attach or insert extract (Eg: Assessor Snapshot Report)

**SCHEDULE 2: FUNDING CONDITIONS**

(If Funding Conditions are applicable: attach Schedule/detail as applicable; otherwise insert ‘Not Applicable’.)

**SCHEDULE 3: NOTICE AND CONTACT DETAILS**

**A. Administering Institution: <NAME>**

|  |  |
| --- | --- |
| Notice details | |
| Notice contact name | <Insert Name> |
| Position | <Insert Title> |
| Physical address | <Insert Address> |
| Postal address | <Insert Address> |
| Email | <Insert email> |
| Invoicing details | |
| Invoicing contact name | <Insert Name> |
| Position | <Insert Title> |
| Address | <Insert Address> |
| Email | <Insert email> |
| Acquittals details (person/unit) | |
| Acquittals contact name | <Insert Name> |
| Position | <Insert Title> |
| Address | <Insert Address> |
| Email | <Insert email> |

**B. Participating Institution <NAME>**

*(Notice details should be provided in all instances. Invoicing and Acquittals details should be provided where the Participating Institution is in receipt of NHMRC funding as set out in Table 1)*

|  |  |
| --- | --- |
| Notice details | |
| Notice contact name | <Insert Name> |
| Position | <Insert Title> |
| Physical address | <Insert Address> |
| Postal address | <Insert Address> |
| Email | <Insert email> |
| Invoicing details | |
| Contact name | <Insert Name> |
| Position | <Insert Title> |
| Address | <Insert Address> |
| Email | <Insert email> |
| Acquittal details (person/unit) | |
| Contact name | <Insert Name> |
| Position | <Insert Title> |
| Address | <Insert Address> |
| Email | <Insert email> |

**SCHEDULE 4: PROJECT CONTRIBUTIONS**

As set out in the Application unless otherwise specified below.

**ANNEXURE 1: Medicines Australia CTRA Schedule 4 Special Terms for clinical trials funded under the NHMRC Funding Agreement, which have been approved for the University of Sydney by the Southern and Eastern Border States (SEBS) – Queensland, New South Wales, Victoria and South Australia**

For the duration of the Funding Period, the Institution agrees to use its best endeavours not to do anything that causes the CRG to breach its obligations under the Funding Agreement and Conditions of Award between the Commonwealth of Australia as represented by the NHMRC: [insert URL for relevant Funding Agreement template] (Funding Agreement) which the CRG entered into for the Study, in so far as those obligations apply to the Institution.

All capitalised words and phrases used in this Schedule 4, if not defined in this Agreement, have the same meanings as set out in the Funding Agreement.

In particular, the Institution agrees:

a) to notify the CRG of any allegations of Research Misconduct or Conflict-of-Interest involving any of its Specified Personnel during the course of the Study and cooperate with the CRG to comply with any steps reasonably required by the NHMRC to resolve or otherwise deal with such allegations of Research Misconduct or Conflict-of-Interest;

b) to inform each of its Specified Personnel prior to his/her involvement in the Study that their Personal Information may be disclosed to the CRG and the NHMRC under clause 16 of the Funding Agreement;

c) if required by the NHMRC, to repay to the CRG any Funds provided by the CRG to the Institution for the Study that the Institution has not spent or legally committed for the Study in accordance with this Agreement;

d) where the NHMRC terminates or reduces the scope of the Funding Agreement, any early termination fees set out in Schedule 2 of this Agreement will not exceed the amounts paid to the CRG from the NHMRC under clause 14.3 of the Funding Agreement;

e) to grant the CRG a permanent, irrevocable, free, world-wide, non-exclusive licence (including the right of sub-licence) to use the Incorporated Material they own or have rights to control and license to others to satisfy clause 12.5 of the Funding Agreement;

f) to arrange for each of Institution’s Specified Personnel to provide the consent required by the NHMRC in relation to those authors’ Moral Rights in accordance with clauses 12.6, 12.7 and 12.8 of the Funding Agreement;

g) to provide information that the CRG is required to provide in compiling the Reports required under clause 9 of the Funding Agreement in relation to the Study;

h) to provide the Commonwealth access specified in clause 4.7 of this Agreement; and

i) to use the NHMRC logo and acknowledge the Funding consistently with the requirements of clause 20 of the Funding Agreement.