**MULTI-INSTITUTIONAL AGREEMENT**

**for**

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

**<insert scheme name> Grant**

**AGREEMENT DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Application NHMRC ID:** | **APP <Insert NHMRC ID>** | **First Funding Year** | **2023** |
| **Scheme:** | **NHMRC <Insert Scheme Name>** | | |
| **Project Title:** | **<Insert Project Title>** | | |
| **Start Date:** | **<insert date in dd/mm/yy format>** or insert <the date this Agreement is executed by the last Party>. | | |
| **Funding Period:** | **<insert >** | | |
| **Funding:** | **<Insert total amount funded>** | | |
| **Administering Institution and its Chief Investigators (CIs)** | **<Insert Institution>** | **<insert name of CI>** | |
| **Participating Institutions and their Lead Investigator.**  **For institutions named on the application, this is usually the first named Chief Investigator (CI) (Specified Personnel) or First named Associate Investigator (AI):** | | | |
| **Institution** | **Lead Investigator** | **Email address** | |
| **<Insert Institution>** | **<Insert name of Lead Investigator>** |  | |
| **<Insert Institution>** | **<Insert name of Lead Investigator>** |  | |
| **<Insert Institution>** | **<Insert name of Lead Investigator>** |  | |
| **<Insert Institution>** | **<Insert name of Lead Investigator>** |  | |
| **<Insert Institution>** | **<Insert name of Lead Investigator>** |  | |
| **<Insert Institution>** | **<Insert name of Lead Investigator>** |  | |
| **Do the Clinical Trial provision of this agreement apply?** | **Yes** | **No** | |
| **Clinical Trial/CTC terms – refer PART C** | Applicable if the Administering Institution nominates their applicability above.  In general these provision should be applied in cases where:   1. the Scheme identified above is the NHMRC Clinical Trials and Cohort Studies Grant; or 2. the Project involves a Clinical Trial (as defined in Part C Clinical Trials and confirmed below). | **Sponsor:**  *[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.]* | |

**BACKGROUND**

1. The Commonwealth as represented by the National Health and Medical Research Council (**NHMRC**) recognises the importance of fundamental research to the national innovation system and supports research through its funding schemes, including the Scheme.
2. The Administering Institution, with the support of the Participating Institutions, successfully applied for Funds under the Scheme for the purposes of the Project.
3. Under the Funding Agreement, the NHMRC requires that the Administering Institution to enter into a formal agreement prior to commencing activities under the Project, and the Participating Institutions agree to perform the Project on the terms and conditions within this Agreement and the Funding Agreement.

**These Agreement Details and the following terms and conditions are agreed to by the Parties:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Institution** | **Name of Lead Investigator.**  **(see definition in Agreement Details)** | **Name and Signature of Authorised Signatory** | **Date of signing by Authorised Signatory** |
| **<Insert name of Administering Institution>** | **< CI Name>** |  |  |
| **<Insert name of Participating Institution>** | **< CI Name>** |  |  |
| **<Insert name of Participating Institution>** | **< CI Name>** |  |  |
| **<Insert name of Participating Institution>** | **< CI Name>** |  |  |

**THE PARTIES AGREE TO THE FOLLOWING TERMS AND CONDITIONS**

***PART A CONDUCT OF PROJECT***

1. DEFINITIONS
   1. Unless otherwise defined in this clause 1, the Agreement Details or Part C of this Agreement, capitalised terms have the same meaning as set out in the Funding Agreement (but interpreted in the context of this Agreement), and the interpretation provisions of the Funding Agreement apply to the interpretation of this Agreement as the context allows.
   2. In this Agreement:

**Agreement** means this agreement 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 Materials** meansthe biological materials or samples (including any tissue, blood or other biospecimen) belonging to or under the control of a Party, which are made available for, agreed to be provided under or collected as part of, the Project and includes unmodified derivatives of the Biological Material and information related to that Biological Material. Unmodified derivatives comprises unmodified material that is propagated from, derived from or based upon the Biological Material, whether or not progeny.

**Data** means data, datasets, databases, results, and other information.

**Existing Material** means all Material and Data that is in existence prior to the Commencement Date specified in the Schedule or otherwise created independently of the Project, which a Party decides to make available to carry out the Project.

**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.

**Funding Agreement** means the agreement between the NHMRC and the Administering Institution regarding Funding, as amended from time to time. The Parties agree that they have received a copy of the Funding Agreement, which as at the date of this Agreement can be accessed at <https://www.nhmrc.gov.au/funding/manage-your-funding/funding-agreement-and-deeds-agreement>.

**Improvements** mean any improvements, variations, modifications, developments (including new uses) or adaptations made to a Party’s Existing Material as a result of its use in the Project but does not include any intellectual property that can be used or exercised without infringing the relevant Existing Material.

**Material** includes any material, documentation, information, Data, results, samples, reports in whatever form held, and any conclusions, discoveries, methods, inventions, know-how, processes, techniques, algorithms, methodology, systems, code software, Data and the like, whether patentable or not.

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

**Project** means the project named in the Agreement Details and more specifically detailed in Schedule 1.

**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.

**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 excludes Improvements to Existing Material, a Student’s thesis or work submitted for a higher degree and if relevant, excludes Study Materials (as that term is defined in clause 12.1, Part C).

**Specified Personnel** means, in respect of a Party, the persons named in the Agreement Details, and such other persons as may be approved by the Parties to perform all or part of the Project from time to time.

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

* 1. If there is any inconsistency between:

1. the Funding Agreement;
2. Agreement Details;
3. any clinical trial agreement entered into separately by a Party in respect of a Clinical Trial that forms part of the Project;
4. Part C Clinical Trial;
5. Parts A and B of this Agreement;
6. any schedule, attachment or annexure; and
7. documents incorporated by reference and not referred to above,

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

1. CONDUCT OF PROJECT
   1. This Agreement commences on the Start Date 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 the NHMRC (if required) or terminated earlier in accordance with this Agreement.
   2. The Parties agree:
2. that the roles, budget, contributions and research activities of each of the Parties in relation to the Project as at the date of this agreement are set out accurately in Schedule 1 of this Agreement;
3. to each carry out their roles, responsibilities and research activities and provide their Project Contributions as set out in this Agreement or as varied from time to time with the prior approval of the Parties and the NHMRC (if required);
4. to carry out the Project in an ethical, responsible, diligent and competent manner, including if relevant, complying with the *NHMRC National Statement on Ethical Conduct in Human Research (2007) – updated 2018* or its replacement, and any other relevant NHMRC standard, publication or guideline that relates to human research;
5. to ensure that the Project is performed and completed within the Funding Period, unless otherwise varied by the NHMRC in accordance with the Funding Agreement;
6. to ensure that their Specified Personnel perform the Project in accordance with this Agreement;
7. 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;
8. to cooperate with each other, in good faith in relation to any complaints or allegations about potential breaches of the *Australian Code for the Responsible Conduct of Research* (2018), including Research Misconduct;
9. that any Institutional Approval, including statements of compliance and/or ethics clearance necessary for the performance of research activities under the Project 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;
10. to comply with the requirements of the Australian Privacy Principles under the *Privacy Act 1988* (Cth) and such other relevant laws, regulations, codes or guidelines prevailing in the jurisdiction in which the Project is being undertaken or which applies to a Party in relation to the use, collection, storage and security or disclosure of any personal and/or health information collected or used during the Project;
11. 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 Legislation;
12. that the payments of salaries for Personnel, where applicable, will be made in accordance with the Funding Agreement and the relevant employing institution’s human resources policy;
13. to ensure that it and with its best endeavours, its subcontractors will comply with all applicable laws, statutes and regulations in respect of modern slavery (including not using any form of child labour, bonded labour, forced labour nor other forms of slavery or slavery-like conditions or human trafficking) and each Participating Institution warrants that it has not been convicted of any offence involving modern slavery nor has it been the subject of any investigation, inquiry or enforcement proceedings by any governmental or regulatory body regarding any offence or alleged offence in connection with modern slavery; and
14. to comply with any applicable statutes, regulations, by-laws and requirements of the Commonwealth and any State, Territory or local authority, including *Australia’s Foreign Relations (State and Territory Arrangements) Act 2020* (Cth).

***Application of Funding Agreement***

* 1. In carrying out the Project and using the Funds, each Participating Institution agrees:

1. to, and to ensure that its Specified Personnel, abide by the terms and conditions of the Funding Agreement, the NHMRC funding Policy and any applicable Funding Conditions (specified in Schedule 2 of this Agreement), and all applicable NHMRC Approved Standards and Guidelines (including obtaining, maintaining and complying with any Institutional Approvals) to the extent that they relate to the Participating Institution, including complying with the following terms of the Funding Agreement:
   1. clauses 4.7 and 4.8 regarding access to locations, cyber security and data breaches;
   2. clause 8 Record Keeping;
   3. clause 9 Reports;
   4. clause 11 Access to premises and documents;
   5. clause 13 Assets;
   6. clause 20 Acknowledgements of NHMRC funding and use of NHMRC logo;
   7. clause 21 Use of Information; and
   8. clause 31.4 notice regarding certain circumstances,

as though the terms were expressly set out in this Agreement, and where the context allows, a reference to NHMRC is a reference to the Administering Institution and the NHMRC, and a reference to the Administering Institution is a reference to each Participating Institution.

1. to do all things reasonably required to assist the Administering Institution to meet its obligations under the Funding Agreement and not to in any way impede or prevent the Administering Institution from complying with any of its obligations under the Funding Agreement;
2. 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
3. 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.
4. PROJECT FUNDING
   1. Subject to the Administering Institution receiving the Funding, the Administering Institution will retain, and distribute to the Participating Institution(s), the Funding in accordance with Schedule 5, Table 1. All references to dollars in this Agreement are to Australian dollars and Funding will be paid in Australian dollars.
   2. Where the Administering Institution distributes Funding to a Participating Institution, that Participating Institution will:
5. only spend the Funding on the Project;;
6. 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;
7. 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;
8. If a purchase order is required for invoicing, the Administering Institution will provide this within 30 days of signing the Agreement otherwise an invoice can be submitted minus the purchase order and the Administering Organisation will use its best endeavours to pay without a purchase order;
9. 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 Funding Agreement except that the Participating Institution is required to provide information to, and seek approval from, the Administering Institution rather than the NHMRC;
10. repay to the Administering Institution any Funds provided by the Administering Institution to the Participating Institution that the Participating Institution has not spent in accordance with this Agreement within 30 days from notice by the Administering Institution; and
11. 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 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).
12. INTELLECTUAL PROPERTY

***Existing Material***

* 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 and such Improvements are licensed on the same terms as Existing Material.
  2. Each Party grants to each other Party a royalty-free, world-wide, non-exclusive, non-transferrable licence to use its Existing Material to the extent necessary to carry out the Project including a right to sublicense the Existing Material to its subcontractors subject to the prior written approval of the Party making available the Existing Material, and if necessary, a right to use the Existing Material for the Project in the event the granting Party withdraws from the Project pursuant to clause 9.3. 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 Funding Agreement.
  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.

***Project IP***

* 1. The Parties agree that all rights, title and interest in the Project IP (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. In cases where the Project involves a Clinical Trial 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 to the Sponsor of the Study. In the case of jointly owned Project IP, the relevant Parties will own the Project IP as tenants in common in shares proportionate to their respective intellectual contributions to the development or creation of that Intellectual Property.. Each Party assigns its rights, title and interest in Project IP, to the relevant other Party/ies upon creation, as required for the Project IP to be owned in accordance with this clause 4.5.
  2. 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 and requires the Student to comply with clauses 4, 6 and 7 before the Student commences any part of the Project.
  3. The administration and management of the Project IP will comply with the NHMRC’s *National Principles of Intellectual Property Management for Publicly Funded Research*.
  4. The Parties each agree to ensure that their respective staff and Students working on the Project promptly provide to the Administering Institution and Project IP owners 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.
  5. The Party/ies who own Project IP will decide what (if any) measures should be taken to protect the Project IP and will only commercialise Project IP as agreed between the owners.
  6. The Parties will negotiate in good faith and use 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:
     1. for the payment to Parties of a share of any commercialisation benefits received having regard to the contributions to the creation of the Project IP;
     2. for licences to Existing Material owned by a Party where the use or exploitation of the Project IP is reliant on such Existing Material; and
     3. to meet any costs associated with the protection and registration of the Project IP.
  7. Having regard to any requirements to protect potentially commercially valuable Project IP and the rights of Parties in their Existing Material, the Party/ies who own Project IP and Study Material grants to each other Party a non-exclusive, non-transferable, perpetual, royalty free, worldwide licence to use the Project IP and Study Material they own during the Project and after completion of the Project for:
     1. non-commercial research, education and training purposes; and
     2. publication purposes (subject to clause 6 of this Agreement).
  8. Any licences referred to in clause 4.11 includes a royalty-free licence to use any of that Party’s Existing Material to the extent necessary for each other Party to exercise the Project IP and Study Material where any Existing Material is incorporated in or necessary for the use of the Project IP and Study Material.
  9. 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 Study Material they own which is included in Research Material or Incorporated Material to satisfy 12.5 of the Funding Agreement.

***Moral Rights***

* 1. 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 Funding Agreement.

***Indigenous Knowledge***

* 1. The Parties will respect and not assert ownership rights in Indigenous cultural intellectual property rights (**ICIP**) and traditional knowledge including knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity (**Traditional Knowledge**) A Party collecting ICIP or Traditional Knowledge must consult with and seek consent from the relevant traditional custodians for use of such ICIP and Traditional Knowledge, and the Parties must comply with the conditions of any consent obtained by the collecting Party.

1. BIOLOGICAL MATERIALS
   1. During the Project, if a Party (**Material Provider**) transfers Biological Materials to another Party (**Material Recipient**), the Material Recipient must:
2. only use the Biological Material for the purpose of the Project;
3. not provide the Biological Material to any third party unless with the prior written consent of the Material Provider;
4. not use the Biological Material in humans, 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 Material Provider and the Administering Institution;
5. not seek any form of registration of Intellectual Property or other statutory protection of the Biological Material;
6. not seek to reverse engineer the Biological Material or otherwise determine the origin of the Biological Material (unless otherwise expressly agreed by the Material Provider);
7. comply with all applicable laws, regulations, codes and guidelines in relation to use of the Biological Material;
8. obtain all ethical clearances that are necessary or desirable to use the Biological Material for the purpose of the Project;
9. ensure that its employees, students, contractors and officers use the Biological Materials in accordance with the terms of this Agreement and the relevant human subject consent;
10. co-operate with the Material Provider and act reasonably in connection with this Agreement and receipt of the Biological Material; and
11. must, at the expiration or termination of this Agreement, at its own cost, return, transfer or dispose of all remaining Biological Materials as instructed by the Material Provider.
    1. The Material Recipient acknowledges and agrees that, as between the Parties, the Material Provider retains title to the Biological Material provided to the Material Recipient under this Agreement.
    2. The Material Recipient acknowledges and agrees that:
12. the Biological Material is experimental in nature and may have defects, deficiencies and hazardous properties. The Material Provider does not make any representation or give any warranty that the Biological Material is fit for any particular purpose;
13. the Material Provider does not make any representation or give any warranty that the use of the Biological Material by the Material Recipient or transfer of the Biological Material to the Material Recipient will not infringe the Intellectual Property or other rights of any third party;
14. the Biological Material is provided on an “as is” basis. 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 Material Provider or the Administering Institution in relation to the Biological Materials are expressly excluded under this Agreement; and
15. except as otherwise provided in clauses 4 and 5, nothing in this Agreement grants the Material Recipient a licence or assigns to the Material Recipient any Intellectual Property of the Material Provider.
16. puBLICATIONS
    1. Subject to clause 7.1, on request, each Participating Institution agrees to provide the Administering Institution with any publications resulting from the Project and its related data in order for the Administering Institution to comply with the obligations under clauses 12.9 and 12.10 of the 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 Student’s thesis to a minimum and not to exceed any maximum period set out in the enrolling institution’s applicable regulations, by-laws and procedures.
    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:
17. 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 Funding Agreement;
18. a Party requests that the proposed publication be amended, the publishing Party will use all reasonable efforts to amend the proposed publication accordingly; and
19. if requested, delay submission of the publication for a period not exceeding 6 months to allow appropriate registration of any registrable Intellectual Property after which the publishing Party can submit the proposed publication subject to any applicable requirements under the Funding Agreement.
20. 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:
21. the Administering Institution may disclose Confidential Information including the terms of this Agreement, if required by the NHMRC under the terms of the Funding Agreement;
22. 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 is bound to keep the information in confidence; and
23. 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.
    1. 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.
24. 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 Project.
    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 comply with clause 29 of the Funding Agreement, including notifying the Administering Institution if the events in clause 29.2 occur and comply with any steps reasonably required by the Administering Institution and the NHMRC to resolve or otherwise deal with that Conflict of Interest under clause 29 of the Funding Agreement.
25. TERMINATION AND REDUCTION
    1. The Administering Institution may terminate this Agreement if:
26. the NHMRC ceases to provide the Funding or the 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
27. 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:
28. at any time by the Parties mutual written agreement;
29. if the Project is wholly terminated;
30. by a Party if required under law or Ministerial direction or if it puts that Party in breach of a law, regulation or Ministerial direction, including under the Australia’s *Foreign Relations (State and Territory Arrangements) Act 2020* (Cth); or
31. terminated in accordance with clause 9.1.
    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 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 or approves suspension of the scope of the 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 or suspended, or alternatively the Parties will agree on a new funding distribution.
    3. Upon termination, reduction or suspension, the Parties will stop, reduce or suspend performance of the Project, take all reasonable steps to minimise loss resulting from the termination, reduction or suspension, continue to perform any Project obligations which are not affected by the reduction or suspension, and a 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.
    5. The following clauses of this Agreement will survive the expiration or earlier termination of this Agreement: 1, 2.2(i), 2.2(j), 2.3, 3.2, 4, 5, 6, 7, 9.5, 9.6, 10, 11.1, 11.2, 11.3, 11.9, and if applicable Part C, along with any other provision which by its nature survives termination or expiration of this Agreement.

***PART B INDEMNITY, LIABILITY, AND GENERAL TERMS***

1. INSURANCE, INDEMNITY AND LIABILITY
   1. In respect of any claim the NHMRC makes against the Administering Institution under clause 18 Indemnity of the Funding Agreement, each Participating Institution indemnifies the Administering Institution on the same terms as though that clause 18 is set out in full in this clause 10.1. References in that clause 18 to Administering Institution is a reference to each Participating Institution and a reference to the NHMRC is a reference to the Administering Institution and the NHMRC.
   2. 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.
   3. The Parties will have the equivalent insurance required of the Administering Institution under clause 19 of the Funding Agreement.
   4. 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:
2. the relevant limitation or exclusion does not apply to that loss or damage; and
3. 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).
4. GENERAL

***Dispute***

* 1. If any dispute or difference arises in connection with this Agreement, then the Parties will negotiate in good faith using their best endeavours to resolve the dispute or difference (except in respect of any action for urgent interlocutory or equitable relief). 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. In doing so, the Parties will comply with the procedure set out in clause 30 of the 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.

***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.

***Other***

* 1. This Agreement may be signed electronically or in any number of counterparts which together will constitute one agreement.
  2. Each Party may communicate its execution of this Agreement by successfully transmitting an executed copy of this Agreement by email to the other Party.
  3. 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.
  4. No addition to or modification of any provision of this Agreement shall be binding upon the Parties unless by written agreement signed by each of the Parties.
  5. 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.
  6. 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.
  7. 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.
  8. 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.
  9. This Agreement:

1. contains the entire agreement of the Parties; and
2. 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).

***PART C CLINICAL TRIALS*** (These terms only apply if the Project is funded under the NHMRC Clinical Trials and Cohort Studies Grant or if the Project involves a Clinical Trial)

1. Definitions
   1. Where a capitalised term is defined in this Part C, that defined term will prevail over any inconsistent definition in the Agreement Details or Part A, and this Agreement is interpreted using the following definitions in this Part C:
2. **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;
3. **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;
4. **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;
5. **Grant Guidelines** means the NHMRC Clinical Trials and Cohort Studies Grants 2019 Guidelines as amended from time to time. The Grant Guidelines can be accessed at <https://www.grants.gov.au/Go/Show?GoUuid=6d813981-c0bb-495c-bc97-3eb2805436a9> or it’s replacement.
6. **Institution** means the hospital or clinic at or having control of the Study Site;
7. **Medicines Australia CTRA** means the current version of the Medicines Australia Clinical Trial Research Agreeme–t - Collaborative or Cooperative Research Group (CRG) Studies – Standard Form. The Medicines Australia CTRA can be accessed at <https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/>;
8. **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-investigation-research-agreements>;
9. **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;
10. **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;
11. **Responsible HREC** means the Human Research Ethics Committee(s) reviewing the Study on behalf of the Institution;
12. **Study** means that part of the Project to be conducted in accordance with the Protocol, which has been determined to be a Clinical Trial;
13. **Study Material** means all the Materials and information created or arising in the course of the conduct of the Study and includes all data, results, Biological Materials, 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;
14. **Study Participant** means a person recruited to participate in the Study as a subject of the Study; and
15. **Study Sites** means the location(s) where the Study is actually conducted,

and all other capitalised terms will have the same meaning as specified in the Agreement Details, Part A or the Funding Agreement.

1. PARTIES’ OBLIGATIONS AND CONDUCT OF STUDY
   1. 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.
   2. Each Party agrees to:
2. 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:
3. the Protocol;
4. the Grant Guidelines (if Project is funded under the Clinical Trials and Cohort Studies Grants scheme), including providing the Administering Institution with reasonable assistance to enable the Administering Institution to report to the NHMRC against milestones and performance indicators as required under the Grant Guidelines;
5. any relevant Commonwealth and State or Territory laws and any requirements of Regulatory Authorities;
6. the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)* as adopted by the Therapeutic Goods Administration;
7. 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
8. 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;
9. keep all Biological Materials which are the subject or outcome of the Study in appropriate storage conditions in areas accessible only to authorised personnel; and
10. maintain complete and current records (including data and reports) in relation to its performance of the Study and ensure that records are retained and preserved for at least 15 years from completion of the Project.
    1. If any issue relating to the safety of Study Participants arises which requires a deviation from the Protocol, the Sponsor of the Study may immediately make such a deviation without breaching any obligations under this Agreement. If there is a need for such a deviation the Sponsor of the Study 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.
    2. The Sponsor of the Study may immediately cease carrying out the Study if it believes on reasonable grounds that continuing the Study poses an unacceptable risk to the rights, interests, safety or well-being of Study Participants without breaching any obligations under this Agreement. The Sponsor of the Study will promptly notify the other Parties if the Study ceases and the Parties will negotiate in good faith and in consultation with the Responsible HREC on how to proceed with the Project (including whether the Project should be varied or abandoned), subject to any requirements under the Funding Agreement.
11. SPONSOR OBLIGATIONS
    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):
12. ensure that the Study is registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) or equivalent before recruitment of the first Study Participant;
13. enter into an agreement with each Institution which, in the case of medicines, would be substantially in the terms of the 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 Funding Agreement, which are included in Schedule 1 of this Agreement or future updated versions; and
14. ensure that the terms of any agreements with third parties are consistent with and contain the relevant terms of this Agreement for the benefit of the Parties, including in respect of licensing of Intellectual Property Rights, confidentiality and publication.
15. publications
    1. Without limiting clause 6 Publications in Part A of this Agreement, the Parties agree that:
16. a Party may not publish any Study Material without the prior written consent (not to be unreasonably withheld) of:

(i) the Sponsor of the Study that is a Party; or

(ii) if the Sponsor of the Study is not a Party, the prior written consent of the Party that subcontracts a third party to act as the Sponsor of the Study, which Party must obtain the prior written consent of such third party Sponsor; and

1. if a publishing Party does not receive a response to a request to publish from the Sponsor of the Study or the Party that subcontracts the third party Sponsor of the Study (as relevant) within 14 days of the request, consent is deemed granted.
2. INSURANCE AND LIABILITY
   1. 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 reasonably incur in conducting the Study or performing its obligations under this Agreement.

**SCHEDULE 1 Project Details**

[*drafting note: Please choose option 1 attach Application or option 2 insert project schedule:*

***Option 1 - attach Application and retain if clinical trial/CTC scheme is applicable*PART C Clinical Trials – refer clause 14.1(b) of the Agreement**

**Medicines Australia CTRA Schedule 4 Special Conditions for clinical trials funded under the NHMRC funding Agreement, must be included in the CTRA at Schedule 4**

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: <https://www.nhmrc.gov.au/funding/manage-your-funding/funding-agreement-and-deeds-agreement> (**Funding Agreement**) which the CRG entered into for the Study, in so far as those obligations apply to the Institution. The Institution agrees to provide reasonable assistance to the CRG to meet its obligations under the Funding Agreement.

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 their 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, and also to grant a sublicence to (name of Administering Institution if they are not the Sponsor of the Study) and (names of Participating Institutions if they are not the Sponsor of the Study) for the purposes of the Project;

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.

*End of Option 1*

***Option 2: insert Project schedule***

|  |  |
| --- | --- |
| * + - 1. Project Title |  |
| * + - 1. Project Start Date |  |
| * + - 1. Project End Date |  |
| * + - 1. Project Aims |  |
| * + - 1. Project Activities | Administering Institution   * Insert specific details about the research activities to be undertaken by the administering institution   [Participating Institution short form name]   * Insert specific details about the research activities to be undertaken by the participating institution   [Participating Institution short form name]   * Insert specific details about the research activities to be undertaken by the participating institution   etc |
| * + - 1. Project Deliverables | Administering Institution   * Insert specific details of deliverables of the administering institution   [Participating Institution short form name]   * Insert specific details of deliverables of participating institution for Project   [Participating Institution short form name]   * Insert specific details of deliverables of participating institution for Project   etc |
| * + - 1. Project Milestones | Administering Institution   * Insert milestone type, due date, reporting process   [Participating Institution short form name]   * Insert milestone type, due date, reporting process   [Participating Institution short form name]   * Insert milestone type, due date, reporting process   etc |
| * + - 1. Project Personnel | Administering Institution      [Participating Institution short form name]      [Participating Institution short form name]      etc |
| * + - 1. Project Student Involvement (if relevant) | Name of Student(s); Degree type; enrolling Institution |
| * + - 1. Project Materials to be supplied (if required) |  |
| * + - 1. Existing Material to be contributed by parties for purpose of Project (if required) |  |
| * + - 1. Publications | Additional conditions |

**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> |
| Purchase Order number required on invoices | Yes  No |
| 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 details and Acquittal 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 – add 10% GST to invoices | |
| 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> |

|  |  |
| --- | --- |
| ***Bank Account details*** | |
| ***Bank Account Name*** |  |
| ***BSB number*** |  |
| ***Account Name*** |  |
| ***Reference number*** |  |
| ***(IF APPLICABLE) International banking details for payments to be made to overseas entities*** | *BAN (if applicable)*  *SWIFT (if applicable)* |

**SCHEDULE 4 Project Contributions**

As set out in the Application unless otherwise specified below.

**SCHEDULE 5 Distribution of Funding**

**Table 1:**

*[Note: This reflects funding from the Administering Institution to the Participating Institutions].*

*All amounts quoted are ex GST.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Institution Name** | **202x** | **202x** | **202x** | **202x** | **202x** | **TOTAL** |
| **<Insert Administering Institution name>** | **$** | **$** | **$** | **$** | **$** | **$** |
| **<Insert Participating Institution name>** | **$** | **$** | **$** | **$** | **$** | **$** |
| **<Insert Participating Institution name>** | **$** | **$** | **$** | **$** | **$** | **$** |
|  |  |  |  |  |  |  |
| **Total NHMRC Grant (indicative only)** | **$Total** | **$ Total** | **$ Total** | **$ Total** | **$ Total** | **$ Total** |