

THIS RESEARCH COLLABORATION AGREEMENT is made on the date it is executed by the last Party to sign.

PARTIES:

The University of Melbourne ABN 84 002 705 224 a body politic and corporate established in 1853 and constituted under the *University of Melbourne Act 2009 (Vic)* (**University**)

AND

Australian Society for Antimicrobials ABN 31 081 739 370 an incorporated association incorporated in Western Australia under the Associations Incorporation Act 1987 (WA) (Registration Number A1007608Z) (**ASA**)

BACKGROUND:

- A. The University is undertaking the clinical trial known as “Staphylococcus aureus Network Adaptive Program” (SNAP) (**Project**).
- B. ASA is interested in the study of antimicrobials and through AGAR is undertaking ASSOP.
- C. The Parties have agreed to collaborate on the Project in accordance with the terms and conditions set out in this Agreement.

OPERATIVE PROVISIONS:

DEFINITIONS AND INTERPRETATION

- 1.1 In this Agreement unless the contrary intention appears:

AGAR means the Australian Group for Antimicrobial Resistance which is a working group operated by ASA that tests and gathers information on the level of antibiotic resistance in bacteria that cause life threatening infections.

Agreement means this Research Collaboration Agreement, including any schedules and annexures and as may be amended from time to time in accordance with its terms;

ASSOP means the Australian Staphylococcus Sepsis Outcome Program, a surveillance program being undertaken by AGAR through a number of hospitals.

Authorised Representative means the nominated personnel of each Party as set out in the Schedule;

Background Intellectual Property means all Intellectual Property Rights belonging to or under the control of a Party as at the Commencement Date of the Project or developed or created by a Party after that Commencement Date but independently to and separately from this Agreement, which are made available for the conduct of the Project;

Business Day means in relation to anything that needs to be done or received, a day not being a Saturday, Sunday or declared public holiday in Melbourne;

Commencement Date means the date set out in the Schedule;

Confidential Information in relation to a Party, means all knowledge, information (including scientific, business, patient, staff and financial information), inventions, improvements, documents, drawings, samples, devices, demonstrations, trade secrets, know-how and other information of whatever description and all other commercially valuable information of that Party and which that Party regards as confidential to it (or which it designates as confidential) and all copies, notes and records as well as all related information generated by, or that comes into the

Research Collaboration Agreement



possession (howsoever occurring) of, the other Party based on or arising out of any such disclosure, but does not include information which:

- (i) is in the public domain at the time of disclosure to the other Party;
- (ii) is published or otherwise becomes part of the public domain but not in breach of any other obligations of confidence;
- (iii) at the date of disclosure to the other Party was already properly in the possession of the other Party without an obligation of non-disclosure to that Party;
- (iv) is independently created by or on behalf of the other Party by persons who had no knowledge of the disclosed information; or
- (v) is required to be disclosed by law;

GST ACT means the *A New Tax System (Goods and Services Tax) Act 1999 (Cth)*

Intellectual Property Rights means statutory and other proprietary rights in respect of trademarks, patents, circuit layouts, copyright, confidential information and all other rights with respect to intellectual property as defined in Article 2 of the Convention establishing the World Intellectual Property Organisation of July 1967;

Loss has the meaning specified in clause 10.3;

Party means a party to this Agreement, its successors and permitted assigns and persons for whom it is responsible;

Privacy Laws mean Commonwealth and/or State and/or Territory legislation, principles, codes and guidelines in relation to the collection, use, storage and security or disclosure of any Personal Information and/or Health Information (as defined in any applicable Privacy Laws);

Project means the research project described in the Schedule;

Project IP means all Intellectual Property Rights developed or discovered in the course of the Project, including subsisting in Project Material; and

Project Material means any physical, electronic, mechanical, biological or chemical materials (including any tissue, blood or other biospecimen) produced in the conduct of the Project;

Protocol means the protocol titled "Staphylococcus aureus Network Adaptive Platform trial (SNAP)", a copy of which is set out in Annexure 1, 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.

Responsible HREC means the Human Research Ethics Committee reviewing the Project.

Results means the whole genomic sequence raw data for the Study Isolates;

Special Conditions means such conditions as may be specified in the Schedule;

Study Isolates means the copies of the bacterial isolates associated with the episode of infection for the SNAP study for each of the Study Participants

Study Participant means a person recruited to participate in the SNAP study.

Termination Date is the date set out in the Schedule.

1.2 In this Agreement, unless the contrary intention appears:

- (i) the singular includes the plural and vice versa;
- (ii) a gender includes all genders;
- (iii) a reference to an individual, person, corporation, trust, partnership, unincorporated body or other entity includes any of them or any other legal person;

Research Collaboration Agreement



- (iv) reference to a Party includes that Party's employees and authorised sub-contractors and agents;
- (v) a reference to a clause or schedule is a reference to a clause of, or a schedule to, this Agreement;
- (vi) references to the words "**include**" or "**including**" are to be construed without limitation;
- (vii) a reference to legislation or to a provision of legislation includes a modification or re-enactment of it, a legislative provision substituted for it and a regulation or statutory instrument issued under it;
- (viii) reference to an "**agreement**" or "**document**" is to the agreement or document as amended, replaced or otherwise varied, except to the extent prohibited by this Agreement or by that other agreement or document;
- (ix) a reference to writing includes reference to printing, typing and other methods of producing words in a tangible and permanently visible form;
- (x) if a word or expression is given a meaning, other parts of speech and grammatical forms of that word or expression have a corresponding meaning;
- (xi) headings are for convenience only and do not affect interpretation;
- (xii) the recitals form part of this Agreement; and
- (xiii) this Agreement is not to be construed to the disadvantage of a Party because that Party was responsible for its preparation.

1.3 In the event of any conflict or inconsistency the following order of precedence shall apply (in descending priority):

- (i) the Special Conditions;
- (ii) the terms and conditions of the clauses of this Agreement; and
- (iii) the Schedule, and
- (iv) Annexure 1.

2. TERM OF THIS AGREEMENT

2.1 This Agreement commences on the Commencement Date and shall be ongoing until the Termination Date or unless otherwise terminated in accordance with its terms.

3. CONDUCT OF THE PROJECT

Each Party will (and will ensure that all its employees, agents and authorised subcontractors employed or engaged in the Project agree to):

- (i) undertake the Project with all due care and skill to the highest professional standards, in an ethical, responsible, diligent and competent manner, and in compliance with:
 - (A) this Agreement (including the Special Conditions);
 - (B) the Protocol;
 - (C) all Institutional Approvals;
 - (D) any relevant Commonwealth and State or Territory laws and any requirements of Regulatory Authorities;
 - (E) to the extent applicable for the Project, the requirements of the TGA in *Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004)* or its replacement and any other TGA publication or guideline that relates to clinical trials, or other such regulations or

Research Collaboration Agreement



guidances governing the conduct of clinical research in the jurisdiction of the Study;

- (F) to the extent applicable for the Project, the Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice (which replaced the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) with effect from 9 November 2016) as adopted by the Therapeutic Goods Administration and/or the ISO 14155:2011: Clinical investigation of medical devices for human subjects -- Good clinical practice (to the extent applicable);
 - (G) to the extent applicable for the Project, the NHMRC National Statement on Ethical Conduct in Human Research (2007) – updated May 2015 or its replacement, and any other relevant NHMRC publication or guideline that relates to human research; and
 - (H) to the extent applicable for the Project, 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).
 - (I) any reasonable direction given by the University in order to ensure the safe conduct of the Project and compliance with applicable regulatory requirements, including any condition of a Responsible HREC;
- (ii) provide to the University, at its reasonable request, all information, documents and assistance relevant to the Project as may be necessary for the University to fulfil its obligations to the Responsible HREC, a regulatory authority or a funder of the Project, or under applicable laws and regulations in connection with this Agreement or the Project;
 - (iii) implement and maintain quality assurance and quality control systems to ensure that the Project can be conducted, and data generated, documented, recorded and reported in compliance with the requirements of all regulatory authorities, and
 - (iv) ensure that any personal information arising from the Project regarding Study Participants or the Personnel involved in the Project is collected, stored, used and disclosed in accordance with the Privacy Laws and any other applicable legislation, code or guideline and relates to the protection of personal information.

4. PROJECT FUNDING & SUPPLIES

- 4.1 The University will provide funding to ASA as described in the Schedule.
- 4.2 Each Party shall supply in a timely and diligent manner any funds, personnel, equipment, materials and other things necessary to fulfil its responsibilities under this Agreement for the Project.
- 4.3 The ASA will issue a tax invoice and the University will pay the invoice within 30 days of the end of the month in which the invoice is submitted. In this clause, a word or expression defined in the GST Act has the meaning given to it in that Act. The Parties agree and acknowledge that any amount payable under or in connection with this Agreement, including the funding, shall exclude

Research Collaboration Agreement



an amount on account of the GST (if any) payable by the supplying Party in respect of that supply.

5. REPORTING

- 5.1 The Parties will regularly hold meetings, at times to be agreed, to update the other on progress of the Project.

6. INTELLECTUAL PROPERTY

Background IP

- 6.1 A Party's Background Intellectual Property shall remain vested solely in that Party and nothing in this Agreement shall be deemed to give the other Party any rights to use or commercialise the same except as expressly provided by this Agreement.
- 6.2 Each Party:
- (i) agrees that it will not have any claim, ownership or interest in the other Party's Background Intellectual Property;
 - (ii) grants the other Party a non-exclusive, fee and royalty-free licence for the use of any Background Intellectual Property made available by the granting Party for the purpose of carrying out the Project only.
- 6.3 The Parties agree that the Study Isolates and the Results are considered Project IP for the purpose of this Agreement and will be owned by the University upon creation.

7. PRIVACY

- 7.1 Each Party must comply with its obligations under all applicable laws in relation to the collection, storage, use and disclosure of any Personal Information or Health Information (as defined in any Applicable Privacy Laws) which it obtains during the conduct of the Project or to which it becomes privy as a result of this Agreement, including that each Party must only use such information in accordance with the terms of any consent forms required under clause 3.

8. CONFIDENTIALITY AND PUBLICATION

- 8.1 Subject to the remaining provisions of this clause 8, each Party will treat all Confidential Information of any other Party as confidential and will not, without the consent of the other relevant Party, disclose or permit the same either to be disclosed to third parties or to be used, except solely as contemplated by this Agreement.
- 8.2 Each Party must use all reasonable endeavours to ensure that its representatives comply with the obligations of confidentiality imposed upon it under this clause 8 as if those representatives were bound in the same way.
- 8.3 Each Party must advise each other Party as soon as practicably possible of any breach of any confidentiality obligations under this Agreement of which it becomes aware.
- 8.4 A Party may disclose Confidential Information if required to do so by law or to its professional advisers, subject to the relevant adviser being bound by similar obligations of confidentiality, or if necessary, entering into an appropriate confidentiality undertaking.
- 8.5 A Party may publish the Project IP, subject to it complying with the following:
- (i) prior to any publication, the Party must provide the other Party with full details of the Project IP it proposes to publish and the nature of the publication; and
 - (ii) the other Party must notify the first Party whether permission to publish has been granted or refused within 30 days of the request (**Period**); and

Research Collaboration Agreement



- (iii) if the other Party fails to notify the first Party of its decision under clause 8.5(ii) within the Period shall be deemed to have consented to the proposed publication by the first Party; and
 - (iv) any other Party may only refuse a request to publish if, in that other Party's reasonable opinion, the publication is likely to jeopardise:
 - (i) the protection of Project IP (as applicable) under any statute of monopoly; or
 - (ii) the other Party's Confidential Information.
- 8.6 Each Party's obligations under this clause 8 shall survive termination or expiration of this Agreement.
- 9. WARRANTIES**
- 9.1 Each Party warrants that it is the owner of, or has the right to provide and use, its Background Intellectual Property for the Project free from all encumbrances and that to the best of its knowledge and belief at the time of entering into this Agreement, no third party has any rights or claim over the same.
- 9.2 Each Party warrants that, to the best of its knowledge and belief at the time of entering into this Agreement, it is not aware of any matter, fact or circumstance that is likely to adversely affect its ability to meet its obligations in relation to this Agreement, but if, during the term of this Agreement a conflict, or risk of conflict of interest, arises it shall promptly notify the other Party or Parties immediately in writing of that conflict or risk.
- 9.3 Each Party will exercise all reasonable care and diligence in carrying out its obligations under this Agreement and in relation to the Project, but to the fullest extent permitted at law each Party excludes all warranties, conditions or terms, implied in fact or at law, including any warranties that the Project IP are of merchantable quality or are fit for a particular purpose.
- 10. INSURANCE AND INDEMNITIES**
- 10.1 Each Party shall effect and maintain adequate insurance to cover its conduct of the Project.
- 10.2 Each Party uses the Project IP and any Project Materials in accordance with this Agreement at its own risk.
- 10.3 Each Party releases and indemnifies and will continue to release and indemnify the other Party or Parties and its officers, staff and agents from and against all actions, claims, demands, costs and expenses (including the costs of defending or settling any action, claim or demand) (**Loss**) made, sustained, brought or prosecuted in any manner directly based upon, occasioned by or attributable to any injury to any person (including death) or loss of or damage to property (including any infringement of Intellectual Property Rights) which may arise in relation to:
 - (i) the indemnifying Party's use of the Project IP or Project Materials;
 - (ii) or be a consequence of, the indemnifying Party's disclosure or use of any Confidential Information in breach of this Agreement;
 - (iii) any unlawful or negligent act or omission of the indemnifying Party or its representatives under this Agreement;
 - (iv) a breach of the terms and conditions of this Agreement by the indemnifying Party.
- 10.4 The indemnifying Party's liability to indemnify another Party under this clause 10 will reduce proportionately to the extent that any unlawful act or omission, or negligence or wilful misconduct by the indemnified Party or Parties contributed to the loss or damage sustained by the indemnified Party or Parties.
- 10.5 An indemnified Party will use its commercially reasonable efforts to mitigate any Loss that is subject to indemnification under this Agreement. In the event that an indemnified Party fails to

Research Collaboration Agreement



so mitigate a Loss, the indemnifying Party will have no liability for any portion of such Loss that reasonably could have been avoided had an indemnified Party made such efforts.

- 10.6 Notwithstanding any other provision in this Agreement, no Party will be liable to any other Party in connection with this Agreement in contract, tort (including negligence), under statute, under any indemnity, under any action, claim or liability, or under any other basis in law or equity for any Loss of an indirect or consequential nature (including any economic loss, or loss of profits, revenue, production, opportunity, anticipated savings, access to markets, goodwill, reputation, business, or loss arising from business disruption or loss or corruption of data, or penalties imposed by third parties), whether or not such loss, or the possibility of such loss, was foreseeable, could have been contemplated by, or was notified to, the other Party.
- 10.7 The provisions of this clause 10 shall survive expiration or termination of this Agreement.

11. DEFAULT AND TERMINATION

- 11.1 Without prejudice to any other of Party's rights, a Party (**First Party**) may by notice immediately terminate this Agreement if the other Party (**Breaching Party**):
- (i) commits a material breach of this Agreement and, where such breach is capable of remedy, fails, within 14 days after receipt of written notice, to remedy such breach; or
 - (ii) is guilty of any wilful misconduct or wilful neglect in the discharge of its duties under this Agreement; or
 - (iii) seeks relief under any bankruptcy or insolvency law or is the subject of liquidation or winding up proceedings, receivership, bankruptcy or similar, other than for the purpose of and followed by a reconstruction, amalgamation or re-organisation.
- 11.2 Upon receipt of a notice of termination the Breaching Party must:
- (i) stop work as specified in the notice;
 - (ii) take all available steps to minimise loss resulting from that termination and to protect the First Party's Confidential Information;
 - (iii) return to the First Party or destroy, as directed by the First Party, any documents originating from the First Party which embody any First Party Confidential Information and must not keep any copies in any form, with the exception of one copy of same, which may be retained in safe custody (as may be specified by the First Party) for insurance and record purposes only; and
 - (iv) upon request certify that any documents not returned to the First Party have been destroyed in accordance with clause 11.2(iii).
- 11.3 Each Party acknowledges that damages may be an insufficient remedy for a breach by that Party of this Agreement in relation to protecting Confidential Information and that the other Party may be entitled to injunctive or other relief as the circumstances may require.
- 11.4 Notwithstanding other provisions of clause 11, a Party shall not be entitled to exercise its rights and remedies upon the default of the other Party if that default:
- (i) is caused by an act or event that is beyond the reasonable control of that other Party; or
 - (ii) was not reasonably foreseeable at the time this Agreement was fully executed.

Research Collaboration Agreement



11.5 This Agreement may be terminated by mutual agreement in writing between the Parties.

11.6 This Agreement may be terminated by a Party on 60 days written notice.

12. NOTICES

12.1 Any notice, demand, approval, direction, offer, consent, agreement, specification, request, statement or other communication (**Notice**) required to be given or made under this Agreement must be

- (i) in writing, in English;
- (ii) signed by a person duly authorised by the sender; and
- (iii) will be deemed duly given or made if delivered or sent in writing by prepaid post or email or facsimile transmission to the Party's Authorised Representative,

12.2 Any Notice will be deemed to have been received by the Party to which it was sent:

- (i) in the case of hand delivery, upon the date of such delivery;
- (ii) in the case of prepaid post within Australia, on the fourth (4) day following the date of dispatch;
- (iii) in the case of facsimile transmission, at the time of transmission, provided that, following the transmission, the sender receives a transmission report confirming complete error free transmission; or
- (iv) in the case of email transmission, at the time of transmission, provided that, following the transmission, the sender does not receive a notification that the email has not been successfully delivered or the recipient informs sender (and can prove) that it has not received the entire Notice,

but if the result is that a Notice would be taken to be given or made on a day which is not a Business Day, or is later than 4.00 pm (local time), it will be taken to have been duly given or made at 10.00 am on the next Business Day.

12.3 Either Party may change its Authorised Representative, address, email address or facsimile transmission number for the purposes of this Agreement and/or for a Project by giving Notice of such change to the other Party.

13. DISPUTE RESOLUTION

13.1 Except as specified in clause 6, all disputes or differences in relation to this Agreement or its subject matter (**Dispute**) shall be resolved in accordance with this clause 13.

13.2 Upon one Party giving notice of a Dispute arising between the Parties, the Parties agree to negotiate in good faith to resolve the Dispute and will refer resolution of the Dispute to their Authorised Representatives, or their nominees. If the Dispute has not been resolved by negotiation within 10 Business Days or any other period of time agreed by the Parties, either Party may refer the Dispute to mediation and will do so before initiating proceedings in a court to resolve the Dispute.

13.3 A Dispute which is referred to mediation will be referred to the Australian Disputes Centre (**ADC**) and be conducted in accordance with the ADC Guidelines for Commercial Mediation 2015 under the relevant rules in Victoria with the proceedings being in English, and

- (i) if the Dispute has not been resolved within sixty (60) days of referral pursuant to this clause 13.3 any Party to the Dispute may initiate proceedings in a court;
- (ii) any documents produced for the mediation are to be kept confidential and cannot be used except for the purpose of settling the Dispute;

Research Collaboration Agreement



- (iii) each Party must bear its own costs of resolving a Dispute under this clause 13.3; and
 - (iv) unless the Parties otherwise agree, the Parties must bear equally the costs of the mediator.
- 13.4 Nothing in this clause 13 will prevent a Party from seeking interlocutory relief through courts of appropriate jurisdiction. But a Party shall not otherwise commence legal action in the event of a Dispute unless it has first complied with clauses 13.2 to 13.3 inclusive.
- 14. GENERAL**
- 14.1 **Entire Agreement.** This Agreement constitutes the entire agreement between the Parties and supersedes all prior communications, negotiations, arrangements and agreements, either oral or written, between the Parties with respect to the subject matter of this Agreement.
- 14.2 **Variation.** Any modification, alteration, change or variation of any term and condition of this Agreement (including all Schedules) shall only be made in writing and shall be effective upon being executed by both Parties.
- 14.3 **Assignment.** A Party may not assign the rights and obligations arising under this Agreement without the prior written consent of the other Party.
- 14.4 **Counterparts.** This Agreement may be executed in counterparts, each of which shall be an original (and any electronic copy of same will be deemed to be an original), and all counterparts together will be taken to constitute one instrument.
- 14.5 **Relationship.** The Parties are independent contracting parties, and nothing in this Agreement makes any Party the employee, partner, agent, legal representative, trust or joint venture of the other for any purpose whatsoever, nor does it grant either Party any authority to assume or to create any obligation on behalf of or in the name of the other.
- 14.6 **Method of Disclosure.** The obligations of confidentiality in this Agreement apply irrespective of the method of disclosure whether in writing, in computer software, orally, by demonstration, description, inspection or otherwise.
- 14.7 **Burden of Proof.** The burden of showing that any Confidential Information is not subject to the obligations of confidentiality in this Agreement will rest on the recipient of such Confidential Information.
- 14.8 **Costs and Taxes.** Each Party shall bear its own costs and taxes arising out of the negotiation, preparation and execution of this Agreement.
- 14.9 **Further Assurances.** Each Party agrees to do all things and execute all deeds, instruments, transfers or other documents as may be necessary or desirable to give full effect to the provisions of this Agreement and the transactions contemplated by it.
- 14.10 **Severance.** If any provision of this Agreement is invalid or unenforceable, such provision(s) shall be deemed deleted but only to the extent necessary and the remaining provisions of this Agreement shall remain in full force and effect.
- 14.11 **Time of the essence.** Time is of the essence in the performance of any obligation or for anything that is required to be done pursuant to this Agreement.
- 14.12 **Governing Law.** This Agreement is governed by the laws of the State of Victoria and each Party submits to the exclusive jurisdiction of the courts of that State.

SURVIVAL

- 14.13 Any term which by its nature is intended to survive termination or expiry of this Agreement does so survive, including clauses 01, 6, 7, 8, 9, 10, 11, 14.6, 14.7, 14.12 and this clause 014.13.

A handwritten signature in blue ink.

A handwritten signature in blue ink.

Research Collaboration Agreement



Research Collaboration Agreement

Schedule



Item 1	Project	<p>In the case of hospitals that are participating in ASSOP and as Study Sites, AGAR will be provided with a list of Study Participants for such hospitals and will:</p> <ol style="list-style-type: none"> make copies of the bacterial isolates associated with the episode of infection for the SNAP study (Study Isolates), and undertake genomic sequencing of the MRSA Study Isolates and provide the whole genome sequence raw data of the MRSA Study Isolates to the University (Results) <p>The ASA will ship the Study Isolates as notified by University, with the timing for the shipping to depend on recruitment rates for the Study, but which is anticipated to be around every 6-12 months.</p> <p>An AGAR representative will be nominated to attend the SMAP Microbiology working group for the purpose of reviewing and approving all projects that concern the use of the bacterial isolates received from AGAR.</p>
Item 2	Commencement Date	The date upon which this Agreement is last signed by a Party
Item 3	Termination Date	Completion of the Project.
Item 4	Authorised Representatives (<i>clause 1.1</i>)	<p>University:</p> <p>Director of Research, Grants and Contract Services Level 4, Alan Gilbert Building, 161 Barry Street, The University of Melbourne VIC 3010 ric-contracts@unimelb.edu.au</p> <p>ASA:</p> <p>Australian Society for Antimicrobials PO Box 8266 Angelo Street South Perth Western Australia 6151</p> <p>Prof Geoffrey Coombs, ASA President info@asainc.net.au</p>
Item 5	Funding	The University will pay \$10 per Study Isolate and will also cover the cost of shipping the Study Isolates to the University.
Item 6	Special Conditions	None

Research Collaboration Agreement



EXECUTED as an agreement.

SIGNED for and on behalf of the University of Melbourne by its duly Authorised Representative in the presence of:

[Handwritten signature]

Authorised Representative (signature)

[Handwritten signature]
Witness (signature)

Sharon Lewin
Name of Authorised Representative (print)

Felicity Campion
Name of Witness (print)

DIRECTOR
Position

...4 January 2022
Date

SIGNED for and on behalf of ASA (ABN 31081739370) by its duly Authorised Representative in the presence of:

[Handwritten signature]

Authorised Representative

[Handwritten signature]
Witness

Professor Geoffrey Coombs
Name of Authorised Representative

Mr Jacson Chung
Name of Witness

ASA President
Position

11/11/2021
Date

Research Collaboration Agreement
Annexure A to the Research Collaboration Agreement



Project protocol as attached

[Attach protocol if any]