THIS INVESTIGATOR INITIATED CLINICAL TRIAL AGREEMENT (the "**Agreement**") is made on the Effective Date

BETWEEN

Liver Transplant Unit, Austin Health, registered in Victoria under registered number: TBC whose registered office is at Austin Health ("**INSTITUTION**");

AND

NORGINE Pty Limited, registered in New South Wales CAN 005 022 882 whose registered office is at Suite 3.01, 20 Rodborough Road, Frenchs Forest NSW 2086 ("**NORGINE**"). Each of the foregoing may be referred to individually as a "**Party**" and collectively as the "**Parties**".

In the presence of Dr Paul Gow, having offices at Liver Transplant Unit, Austin Health, ("**INVESTIGATOR**").

RECITALS:

A. INSTITUTION wishes to conduct a Trial (as defined in Clause 1) involving human subjects utilising the Product and has approached NORGINE requesting Support (as defined in Clause 1) for the Trial.

B. NORGINE is willing to provide INSTITUTION with Support for the Trial in order to advance medical and scientific knowledge about the Product (as defined in Clause 1) for the benefit of patients, science and medicine, subject to the terms and conditions of this Agreement.

NOW, IT IS AGREED as follows:

1. DEFINITIONS AND INTERPRETATION

1.1. In this Agreement, unless the context otherwise requires, the following words and expressions shall have the following meanings:

"**AE**" or "**Adverse Event**" means any untoward medical occurrence in a patient administered drug that does not necessarily have a causal relationship with the treatment;

"**Affiliate**" means, with respect to a Party, any corporation or other entity that controls, is controlled by, or is under common control with, a Party. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls 50% or more of the voting securities or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity;

"**Applicable Data Protection Law**" shall have the meaning set forth in Clause 10.6.1, and the terms "**controller**", "**personal data**", "**processing**" and "**technical and organisational measures**", and variants thereof, shall have their respective meanings set forth in Applicable Data Protection Law;

"**Background**" means Know-How and Intellectual Property Rights owned or controlled by a Party prior to the Effective Date or developed during the Term but outside the scope of the Trial;

"**Business Day**" means any day other than a Saturday, Sunday or a Bank Holiday in New South Wales and Victoria;

"**Confidential Information**" means all information or data first communicated from one Party, its Affiliates, and its and their employees or representatives, to the other Party, its Affiliates, and its and their employees or representatives whether in writing, orally, including without limitation, all scientific, clinical, technical, commercial, financial and business information, Know-How, compilations, formulae, processes, information, techniques, compounds, formulations, methods of Product delivery, test procedures, stability data, samples, Specifications and other information or data considered confidential in nature by the disclosing Party or its Affiliate;

"**Effective Date**" means the date of execution by the last signatory Party hereto;

"**Ethics Committee**" means the ethics committee(s) responsible for the approval of the Protocol and the Trial;

"**Good Industry Practice**" means in relation to any undertaking and any circumstance, the exercise of that degree of skill, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances;

"**ICH GCP**" means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) together with such other Good Clinical Practice requirements as are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directive including relevant national legislative texts where they have been introduced;

"**Intellectual Property Rights**" means patents, trademarks, trade names, service marks, registered designs, domain names, unregistered design rights, copyright, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;

"**Interventional**" means a clinical trial where the administration of an investigational medical product to the subject or use is subjected to an intervention that would not occur during routine clinical practice or prospectively assigns humans or groups of humans to health-related interventions. These are conducted under the scope of Directive 2001/20/EC and is valid for where no authorisation exists in the EU or post-authorisation clinical trials that fall under the scope due to the nature of the intervention, e.g. for the development of new indications or new formulations;

"**Investigator**" means Dr Paul Gow who is responsible for the conduct of the Trial at the Trial Site and who will comply with all applicable laws and regulations of the Investigator and the Sponsor with respect thereto;

"**Know-How**" means all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submission to Regulatory Authorities, whether or not protected by Intellectual Property Rights or any applications for such rights;

"**Non-Interventional**" means clinical trials conducted under Directive 2001/83/EC and Article 10a (1), (a), (b) of Regulation (EC) No.726/2004, or conducted voluntarily by marketing authorisation holders or other organisations. The assignment of the patient to a particular therapeutic strategy is not decided in advance by the Trial Protocol but falls within current practice. The prescription of the Product in the usual manner in accordance with the terms of the marketing authorisation is clearly separated from the decision to include the patient in the Trial;

"**Primary Data Collection**" studies with a design based on primary data collection directly from healthcare professionals or consumers (i.e. where the events of interest are collected as they occur specifically for the Trial);

"**Product**" means XIFAXAN 550®;

"**Protocol**" means the written protocol ***The Effect of Rifaximin on Sarcopenia and Sepsis in Patients listed for Liver Transplantation*** for the Trial in which INSTITUTION intends to use the Product at the Trial Site;

"**Regulatory Approval**" means any regulatory approvals or permissions required by INSTITUTION to perform their obligations under or in any way connected with this Agreement;

"**Regulatory Authority**" means any governmental regulatory authority or agency involved in regulating any aspect of the activities contemplated by or included within the terms and conditions of this Agreement, including without limitation, the Trial;

"**Secondary Data Collection**" means studies with a design based on secondary use of data (i.e. where the events of interest have already occurred and have been collected for another purpose);

"**Serious Adverse Event**" or "**SAE**" means an Adverse Event that a) results in death, b) is life-threatening, c) results in disability, d) any hospitalisation (exception: elective planned admissions) or prolongation of existing hospital stay, e) congenital anomalies, or f) is considered medically significant;

"**Special Situations**" means when the drug is used during pregnancy, used by the mother during breastfeeding, off-label use, lack of effect, suspected transmission of an infectious agent via a medicinal product, overdose, misuse, (dosage, indication or route of administration deviating from authorised product

label), abuse (intentional, excessive) or medication error (unintentional, e.g. wrong medication by accident, wrong dosage, etc.) and paternal exposure;

"**Sponsor**" means the INSTITUTION, who shall meet the requirements of and fulfil the responsibilities required by applicable laws and regulations with respect to the Trial;

"**Support**" means NORGINE's provision of financial assistance to INSTITUTION as described in Clause 2.2 of this Agreement;

"**Term**" shall have the meaning set forth in Clause 14.1;

"**Trial**" means the clinical trial conducted by the Investigator at the Trial Site using the Protocol; and

"**Trial Site**" means Austin Health

1.2. The headings to clauses of this Agreement are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.

1.3. Where appropriate, words denoting the singular shall include the plural and vice versa; words denoting any gender shall include all genders; and words denoting corporations shall include persons and vice versa.

1.4. Any reference to a statutory provision, code, regulation or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

1.5. Any reference to persons includes natural persons, firms, partnerships, limited liability partnerships, companies, corporations, unincorporated associations, local authorities, governments, states, foundations and trusts (in each case whether or not having separate legal personality) and any agency of any of the above.

2. NORGINE'S ROLE

2.1. As a condition precedent to NORGINE's provision of Support, INSTITUTION shall provide to Norgine prior to the start of the Trial:

2.1.1. the final Protocol;
2.1.2. confirmation of the Ethics Committee approval of the Trial;

2.1.3. confirmation of the Clinical Trial Authorisation relating to the Trial (if applicable);

2.1.4. the curriculum vitae of the Investigator;

2.1.5. the insurance of INSTITUTION in relation to the Trial (if applicable); and

2.1.6. the budget and third party funding (if any) relating to the Trial.

2.2. After NORGINE has received the documents set forth in Clause 2.1 and is satisfied that INSTITUTION has obtained the necessary approvals for the

Trial and that the Support shall be applied solely for the agreed intended research use, NORGINE shall provide INSTITUTION, with Support in connection with the Trial, such amounts not to exceed in total A$10,160.00, which shall be provided to INSTITUTION as follows:

2.2.1. The first instalment of two thousand, one hundred dollars ($2100.00) will be paid following exchange of contracts; and

2.2.2. The second instalment of eight thousand and sixty dollars ($8060.00) will be paid following receipt of Ethics approval.

2.2.3. NORGINE will pay INSTITUTION sixty (60) calendar days from receipt of an invoice accompanied by reasonably supporting documentation, and shall make payment in accordance with any reasonable written payment instructions received from INSTITUTION.

2.2.4. All amounts are in AUD.

2.2.5. NORGINE has not requested the INSTITUTION to conduct this Trial, and INSTITUTION acknowledges that NORGINE may not benefit from the results of this Trial. INSTITUTION further acknowledges that the performance of the Trial does not qualify as a transaction (a service) which is subject to value added tax ("**VAT**"). The obligations of INSTITUTION and the safeguards incorporated in this Agreement with respect to NORGINE's provision of Support do not constitute services. Accordingly, invoices submitted by INSTITUTION to NORGINE hereunder are not subject to VAT.

2.3. NORGINE shall provide any safety information relating to the Product arising during the course of the Trial that affects the safe and ethical conduct of the Trial.

2.4. INSTITUTION acknowledges that the provision of the Support by NORGINE is made for the sole, restrictive purpose of supporting the development or furtherance of bona fide, scientifically valid and legitimate research by INSTITUTION, the purpose of which is to advance medical, scientific and healthcare knowledge, medical technologies and/or clinical techniques designed to improve patient outcomes.

3. INSTITUTION'S OBLIGATIONS

3.1. INSTITUTION shall supply to NORGINE a copy of all the documents in Clause 2.1 of this Agreement prior to NORGINE's provision of Support.

3.2. INSTITUTION agrees to ensure that the Trial is conducted strictly in accordance with the Protocol and any Ethics Committee terms and conditions in a diligent, professional manner commensurate with the highest medical, clinical and research standards consistent with Good Industry Practice and without limiting the foregoing in accordance with all applicable legislation and guidelines including but not limited to:

3.2.1. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use;

3.2.2. ICH GCP;

3.2.3. Applicable Data Protection Law;

3.2.4. The EU Clinical Trials Directive 2001/20/EC, current European Commission Guidelines on reporting adverse reactions from clinical trials, ENTR/CT3 and any related national legislation; and

3.2.5. The EU Good Clinical Practice Directive 2005/28/EC and any related national legislation.

3.3. INSTITUTION shall promptly notify NORGINE in writing if any change(s) are made to the Protocol. If NORGINE reasonably determines that such change(s) materially alter the Protocol, NORGINE may terminate this Agreement on ten (10) Business Days' notice to INSTITUTION, such right of termination exercisable at any time within thirty (30) days following receipt of written notice from INSTITUTION of the change.

3.4. INSTITUTION shall promptly notify NORGINE in writing in the event that the Investigator for any reason is unable to continue to serve in that role (hereinafter referred to as the "**Investigator's Incapacity**"). If the Parties are unable to agree upon an acceptable successor within thirty (30) days following receipt of written notice from INSTITUTION of the Investigator's Incapacity, NORGINE may, subject to applicable laws and regulations, terminate this Agreement on ten (10) Business Days' notice to INSTITUTION, such right of termination exercisable at any time within ten (10) days following receipt of written notice from INSTITUTION of the Investigator's Incapacity.

3.5. INSTITUTION shall supply NORGINE with copies of annual and end of Trial reports including Drug Safety Update Reports generated under EU regulations and Annual IND reports generated under US regulations, if applicable.

3.6. INSTITUTION shall inform NORGINE immediately if there are any limitations placed on the conduct of the Trial by the drug safety monitoring board.

3.7. INSTITUTION and the Investigator shall provide full disclosure of NORGINE's Support in all oral or written presentations of the results of the Trial.

4. LIABILITY

4.1. Neither Party shall be liable either in contract, tort, negligence, statutory duty or otherwise, for any consequential, indirect or special loss or damage whatever arising from or in any way connected with this Agreement (even where advised of the possibility of such loss or damage).

4.2. Nothing in this Agreement shall exclude the liability of either Party for death or personal injury arising from its negligence or that of its servants, agents or employees or any other liability which is prohibited from exclusion by law.

5. QUALITY COMPLAINTS/AEs ARISING FROM QUALITY COMPLAINTS

5.1. INSTITUTION, as Sponsor, shall promptly inform NORGINE of any quality complaints or concerns in relation to Product. INSTITUTION shall communicate such Product complaints or concerns in writing and in the English language, addressed to the responsible NORGINE quality contact individuals designated below:

Designated Norgine Quality Contact	Name: John Oakley Telephone: 02 8422 0800 Fax: 02 9972 7522 e-mail:anzmedinfo@gmail.com
Deputy Norgine Quality Contact	Name: Telephone: Fax: e-mail:

5.2. Quality complaints resulting in a patient experiencing an AE will be processed according to Clause 6.1.

6. ADVERSE EVENTS

6.1. Unless otherwise agreed by the Parties, all recording and reporting obligations set forth in this Clause 6 shall be in the English language, and if required, complaints, reports or other information received in a language other than English will be promptly translated by INSTITUTION into English by a translator experienced in translating medical information.

6.2. INSTITUTION, as Sponsor, shall be responsible for ensuring that all Adverse Events and other relevant safety information are recorded and appropriately reported to the relevant health authorities, Ethics Committees and Trial institutions according to Applicable Laws in the countries where the Trial is conducted.

6.3. INSTITUTION shall report to NORGINE via r following:

- Any findings that might alter the current benefit-risk profile of the Product as soon as it becomes available, but in any event within five (5) calendar days of becoming aware of such information;
- INSTITUTION shall send the final clinical Trial report to NORGINE upon completion of the Trial; and
- INSTITUTION will provide any relevant information from the Trial upon request by NORGINE within five (5) calendar days to enable NORGINE to answer any health authority requests or complete any regulatory documents.

INSTITUTION shall cooperate with all reasonable requests by NORGINE to ensure that all relevant safety information are sufficiently investigated, including requests to seek additional information relating to safety issues and provide upon

request, any relevant safety information required by NORGINE for periodic reports, such as number of patients.

7. REGULATORY APPROVALS

7.1. It shall be the responsibility of INSTITUTION as Sponsor to obtain the clinical trial authorisation ("**CTA**") to the Regulatory Authority.

7.2. It shall be the responsibility of NORGINE to maintain all other necessary Regulatory Approvals which may be required for it to perform its obligations under, or in any way connected with, this Agreement and to comply with all applicable laws and regulations in this respect.

8. INTELLECTUAL PROPERTY

8.1. All Intellectual Property Rights and Know-How relating to the Trial and owned at the date hereof by NORGINE (or a third party and licensed to NORGINE), or otherwise independently developed by NORGINE (or a third party), shall be retained by and remain the property of NORGINE, or such third party as the case may be, and no licence in relation thereto is granted by NORGINE to INSTITUTION.

8.2. Any Intellectual Property Rights or Know-How relating to the Trial and arising from the Trial, shall be owned exclusively by NORGINE. INSTITUTION agrees to provide NORGINE with all necessary assistance to register and/or otherwise give effect to such ownership of the Intellectual Property Rights and / or Know-How. NORGINE shall promptly reimburse INSTITUTION for any of its reasonable out of pocket costs in expenses relating thereto upon receipt of reasonably supporting documentation. For the avoidance of doubt and without limitation, a reference in this Clause 8 to "INSTITUTION" includes and obligates any and all Affiliates of INSTITUTION, and any and all persons and sub-contractors engaged by INSTITUTION who are involved in or providing services with respect to the Trial, including the Investigator.

8.3. Any Intellectual Property Rights or Know-How not relating to the Trial and arising from the Trial shall be owned exclusively by INSTITUTION.

8.4. In the event that any Party owns or controls intellectual property necessary or useful to enable the other Party to practice its Intellectual Property Rights arising under this Agreement, that Party hereby grants to the other Party (including its Affiliates) a non-exclusive, fully paid up, perpetual and irrevocable licence to the intellectual property to the sole extent necessary for the other Party to practice its Intellectual Property Rights arising under this Agreement.

8.5. INSTITUTION shall exercise commercially reasonable efforts to ensure that the sourcing of the Product is accurately acknowledged in the Protocol and in the Trial results. The first mention of the trademark XIFAXAN® in any document shall be accompanied by the statement 'XIFAXAN Product under license from Alfasigma S.p.A. XIFAXAN® is a registered trademark of the Alfasigma group of companies, licensed to the Norgine Group of companies".

8.6. No Party will, without the prior written consent of the other Party, use in advertising, publicity, promotion or otherwise, the name, trademark, logo,

symbol, or other image of the other Party or that Party's employee or agent, except that INSTITUTION may acknowledge NORGINE's financial support of the Trial in academic publications and as required by funding agencies and reports to Regulatory Authorities.

9. FORCE MAJEURE

9.1. Neither INSTITUTION nor NORGINE shall incur any liability to the other in the event of non-performance or delay in the performance of its respective obligations under this Agreement arising out of strikes, disputes (excluding strikes or disputes between INSTITUTION and its employees, contractors and sub-contractors and excluding strikes or disputes between NORGINE and its employees, contractors and sub-contractors), riots, wars (declared or undeclared), fire, acts of terrorism, or any other reasons beyond INSTITUTION's or NORGINE's reasonable control (a "**Force Majeure Event**"), provided however, that the Party whose performance is affected by such Force Majeure Event shall exert its reasonable efforts to eliminate or cure or overcome any such circumstances and to resume performance of its obligations in a timely manner. Any such non-performance shall be excused for the period of such Force Majeure Event.

9.2. Each Party shall give prompt notice to the other upon becoming aware of a Force Majeure Event, such notice to contain details of the circumstances giving rise to the Force Majeure and such Party's plan to eliminate or cure or overcome such circumstances and to resume performance of its obligations. If a Party is unable to overcome such Force Majeure Event within six (6) weeks from the date of receipt of notification by the other Party of its existence, then the Party whose performance is not affected by such Force Majeure Event shall be entitled to terminate this Agreement immediately upon delivery of written notice to the other Party in accordance with Clause 16.1.

10. CONFIDENTIALITY / APPLICABLE DATA PROTECTION LAW

10.1. The Parties undertake and agree to use the Confidential Information solely for the purposes of this Agreement and to keep the Confidential Information secret and confidential and shall not directly or indirectly disclose or permit to be disclosed the same to any third party for any reason without the prior written consent of the other Party hereto.

10.2. The obligations of confidence and nondisclosure of the Parties referred to in Clause 10.1 shall not extend to any Confidential Information which it can be demonstrated:

10.2.1. is or becomes generally available to the public otherwise than by reason of breach by a Party of the secrecy obligations under this Agreement;

10.2.2. is known to the receiving Party and is at its free disposal prior to its disclosure by the disclosing Party;

10.2.3. is developed by the receiving Party independently from the Confidential Information received;

10.2.4. is subsequently disclosed on a non-confidential basis to the receiving Party from a third party having the legal right to make such disclosure in respect of that Confidential Information; or

10.2.5. is required by applicable laws to be disclosed, provided however, that such Party shall, if not contrary to applicable laws, provide notice thereof to the other Party prior to such disclosure and shall limit disclosure to that portion of the Confidential Information which in the opinion of its legal advisers is legally required to be disclosed and then only under obligations of confidentiality to the maximum extent possible.

10.3. In the event one Party becomes aware of any wrongful use or disclosure of Confidential Information (whether inadvertent or otherwise); it shall immediately notify the other Party in writing of that fact and shall provide information regarding all relevant surrounding circumstances.

10.4. After termination of the Agreement the mutual obligations of confidentiality will last for a period of 5 (five) years, except the obligations regarding data protection and data controlling which shall be subject to Applicable Data Protection Law.

10.5. Data protection and data controlling:

10.5.1. The Parties undertake to comply with the applicable laws and regulations on data protection and personal data and, in particular, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 applicable from 25 May 2018, as may be amended or replaced from time to time during the Term and any other applicable national data protection law (hereinafter: "**Applicable Data Protection Law**").

10.5.2. The Parties shall process all personal data in accordance with Applicable Data Protection Law. With respect to the coded data regarding Adverse Events provided to NORGINE, the INSTITUTION and NORGINE are both considered controllers for the processing of the personal data and will both act in accordance with the Applicable Data Protection Law. Furthermore, the INSTITUTION and NORGINE will cooperate with each other to take the necessary measures in order to comply with the Applicable Data Protection Law.

10.5.3. Both NORGINE and INSTITUTION shall implement appropriate technical and organisational measures to meet the requirements of Applicable Data Protection Law.

10.5.4. If either Party becomes aware of a personal data breach, that Party shall promptly notify the other Party. In such a case the Parties will fully cooperate with each other to address the personal data breach and fulfil the (statutory) notification obligations under Applicable Data Protection Law.

11. PUBLICATION RIGHTS

11.1. INSTITUTION shall, subject to the terms of this Clause 11, have the right to publish the results of the Trial in any abstract, paper, presentation or manuscripts (not limited enumeration).

11.2. INSTITUTION shall give NORGINE a reasonable period of 30 (thirty days) to review and comment upon an intended publication of INSTITUTION regarding the Protocol or results of the Trial prior to publication, to determine if any Intellectual Property Rights and/or Confidential Information should be removed. NORGINE shall respond promptly in writing to INSTITUTION with any comments or objections, setting forth such information in reasonably sufficient detail.

11.3. INSTITUTION shall consider NORGINE's comments and/or objections in good faith and shall cause any and all appropriate changes to be made prior to further distribution and publication.

11.4. The obligations contained in this Clause 11 shall survive termination or expiry of this Agreement for a period of five (5) years.

12. INSPECTIONS

12.1. Should competent Regulatory Authority or INSTITUTION conduct or give notice of intent to conduct any inspection at the Trial Site related to the Trial, or take any other action with respect to the Trial, INSTITUTION will promptly give NORGINE notice thereof, and supply all information pertinent thereto. Copies of any reports or findings made by any Regulatory Authority and/or INSTITUTION in relation to the Product shall be promptly provided to NORGINE.

13. INSURANCE

13.1. Each Party shall maintain satisfactory insurance coverage in relation to this Agreement and shall ensure that such insurance coverage remains in full force and effect during the Term and thereafter in accordance with Good Industry Practice and shall not do or omit any act, matter or thing which may prejudice or render voidable any such insurance. Such insurance shall be sufficient to secure the performance of its obligations hereunder. INSTITUTION as the Sponsor shall maintain adequate insurance coverage in accordance with ICH GCP guidelines and applicable laws, rules and regulations.

13.2. If applicable on or before the Effective Date INSTITUTION shall provide NORGINE with a copy of the insurance policy that covers the Trial, and thereafter during the Term upon written request.

14. TERM AND TERMINATION

14.1. This Agreement shall commence on the Effective Date and shall remain in effect until completion of the Trial (the "**Term**") unless sooner earlier terminated in accordance with the terms of this Agreement.

14.2. Either Party may, without prejudice to any of its other rights arising under this Agreement, immediately upon giving notice to the other terminate this Agreement if:

14.2.1. the approval of the competent Ethics Committee that has assessed the Trial is irrevocably revoked;

14.2.2. a reasonable case can be made for terminating the Trial in the interests of the health of the research subjects;

14.2.3. it transpires that continuation of the Trial cannot serve any scientific purpose, and this is confirmed by the Ethics Committee that has issued a positive decision on the Trial;

14.2.4. one of the Parties has been declared insolvent or a bankruptcy/winding-up petition has been filed in respect of such Party, or one of the Parties ceases trading and is dissolved as a legal entity or one of the Parties ceases or threatens to cease paying its debts as they fall due;

14.2.5. the Investigator is no longer capable of performing the tasks of the Investigator, and no replacement agreeable to both Parties can be found in accordance with Clause 3.4; or

14.2.6. one of the Parties fails to comply with the obligations arising from the Agreement and, provided compliance is not permanently impossible, this compliance has not taken place within thirty (30) days of the defaulting Party receiving a written request from the other Party to comply, unless failure to comply is not in reasonable proportion to the premature termination of the Trial.

14.3. On the termination or expiry of this Agreement no further rights or obligations of either Party shall be created but this shall be without prejudice to the rights of each Party accrued prior to such termination or expiry. Clauses which are necessary for the interpretation or enforcement of this Agreement or which are intended by the Parties to survive its termination or expiry, shall survive its termination or expiry, including without limitation Clauses 8 and 11.4.

14.4. In the event of termination above, other than as a result of a material breach by Institution or the Investigator, the financial assistance payable by NORGINE pursuant to this Agreement shall be equitably prorated for actual costs and uncancellable expenses advanced to the date of termination in accordance with the budget set out in Clause 2.2 of this Agreement.

15. ASSIGNMENT

15.1. INSTITUTION shall not be entitled to assign, sub-license, sub-contract or otherwise transfer any of its rights or obligations under this Agreement, whether in whole or in part, without the prior written consent of NORGINE.

15.2. NORGINE shall be entitled to assign, sub license, sub contract, or otherwise transfer any of its rights or obligations under this Agreement to any of its Affiliates without the prior written consent of INSTITUTION, but undertakes to give prior notification of its intention to do so.

16. NOTICES

16.1. All notices and other communications provided for hereunder shall be in writing and shall be delivered by registered mail or certified mail, postage prepaid, or delivered personally, by overnight delivery service or by facsimile, with confirmation of receipt, addressed as follows (or such other address as may be notified by one Party to the other Party from time to time):

If to **NORGINE:**	If to **INSTITUTION**:
Norgine Pty Limited Suite 3.01 20 Rodborough Road Frenchs Forest NSW 2086 Attention John Oakle	Austin Health 145 Studley Road Heidelberg VIC 3084 Attention: Mrs Lisa Pedro, Manager, Ethics and Research Governance, Office for Research Telephone: Email

16.2. Notices delivered by post pursuant to Clause 16.1 shall be deemed to have been served at the expiry of three (3) Business Days from the time of posting and proof that the notice was correctly addressed and posted shall be sufficient evidence of service. Notices delivered by facsimile pursuant to Clause 16.1 shall be deemed to have been served immediately upon completion of transmission if sent on a Business Day during normal working hours, and if not, on the following Business Day, and proof that the transmission was made correctly to the correct facsimile number and was uninterrupted shall be sufficient evidence of service.

17. MISCELLANEOUS

17.1. **Independent Contractor**. The Parties shall at all times act as independent Parties and nothing contained in this Agreement shall be construed or implied to create an agency, joint venture, partnership or business organisation of any kind. Neither Party shall have the authority to assume or create any obligation, express or implied on behalf of the other Party, nor shall either Party represent to anyone that it has such authority. The Parties' respective employees shall not be entitled to any benefits applicable to employees of the other Party.

17.2. **Entire Agreement.** This Agreement constitutes the entire agreement and understanding between the Parties and supersedes all prior oral or written

understandings, arrangements, representations or agreements between them relating to the subject matter of this Agreement provided that this does not remove any right of action by either Party in respect of any fraudulent misrepresentation, fraudulent concealment or other fraudulent action.

17.3. **Agreement Modification/Waiver.** This Agreement shall be amended only in writing duly executed by authorised representatives of the Parties to this Agreement. No waiver by any Party of any default or non-performance shall be deemed a waiver of any subsequent default or non-performance. The single or partial exercise of any right, power or remedy provided by applicable laws or under this Agreement shall not preclude any other or further exercise thereof or the exercise of any other right, power or remedy.

17.4. **Legal Costs.** Each Party shall bear its own legal costs and other expenses incurred in the negotiation, preparation, execution and implementation of this Agreement.

17.5. **Counterparts.** This Agreement may be executed in several counterparts and via fax or electronically by pdf, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

17.6. **Severability**. If any provision of this Agreement is declared by any court or other competent authority to be void, voidable, illegal or otherwise unenforceable this will not affect the other provisions of this Agreement which shall continue to operate and remain in full force and effect.

17.7. **Governing Law**. This Agreement and any non-contractual obligations arising from or in connection with it shall in all respects be governed by and interpreted in accordance with NSW law. The Parties also irrevocably agree that the Courts of NSW are to have exclusive jurisdiction over any dispute (i) arising from or in connection with the Agreement or (ii) relating to any non-contractual obligations arising from or in connection with the Agreement, and hereby submit to such jurisdiction

17.8. **Power & Authority**. Each Party hereby represents and warrants to the other that it has full power and authority to execute, deliver and perform its obligations under this Agreement, and that such Party is not bound by any other contractual obligation, express or implied, inconsistent with the terms hereof.

17.9. **Interpretation**. In the event that there is any inconsistency between the terms of the Protocol and the terms of the Agreement, the terms and conditions of the Protocol shall prevail with respect to all medical matters, the conduct of the Trial and with respect to serving the best interest of patient welfare, and the terms of the Agreement shall prevail with respect to all legal, business and/or commercial financial matters.

IN WITNESS WHEREOF, the duly authorised representatives of the Parties have signed this Agreement as of the Effective Date.

Austin Health	**Norgine Pty Limited**
Signature:……..…	Signature:……..…
Name: ……	Name: ……
Title:……	Title:……
Date: ___/____/_____	Date: ___/____/_____

Read and acknowledged by the **INVESTIGATOR:**

Signature:……..…

Name: ……

Title:……

Date: ___/____/_____