Contract Research Organisation Master Services Agreement

AGREEMENT DETAILS

TERM	MEANING
CRO, we, us or our	**iNGENū Pty Ltd (ACN 656 400 056)** **Address:** Office C2, level 1, 459 Toorak Road, Toorak, 3142 **Email:** enquiry@ingenu.com.au
Sponsor, you or **your**	**Psyence Australia Pty Ltd (ACN 665 259 727)** **Address: Level 7, 330 Collins Street, Melbourne VIC 3000** **Email:** info@psyence.com
Commencement Date	Date of last signature.
Term	This Agreement will start on the Commencement Date and terminate on the End Date. The Parties may extend the Term by mutual agreement, documented in writing.
End Date	This Agreement will end at a mutually agreeable time, unless terminated earlier in accordance with clause 19.
Deposit	The Deposit is as set out in the applicable Study Order (if any).
Expenses	The Expenses are as set out in the applicable Study Order.
Price	The Price for each Study Order is as set out in the applicable Study Order and based upon the Study Budget.
Pass Through Costs	The following costs will be invoiced to you as pass through costs: ● any third party fees and disbursements identified as 'Pass Through Costs' in the Study Budget attached to a Study Order; ● any other third party fees or disbursements, reasonably and directly incurred by us for the purpose of a Study which are approved by you in writing; ● any reasonable costs associated with a Study Participant requiring medical treatment as a result of their participation in a Study; and ● all costs incurred in relation to managing and reporting any adverse events, subject to the provisions of clause 18.
Payment Terms	All undisputed invoices are payable within 30 days of receipt of the relevant invoice, or as otherwise agreed between the Parties.
Required Insurances	At a minimum, you are required to effect and maintain the following insurances for the Term (and for a reasonable period thereafter) and with a reputable insurance provider, occurrence-based policies for: ● Products/Services And Clinical Trials Liability: $10,000,000 each occurrence and in the annual aggregate ● a professional indemnity insurance policy, or equivalent, in the amount of no less than $5 million for any one claim; and ● all other insurances required by Law in order for us to provide you with the Services. We are required to maintain all insurances that could be expected of a prudent, first rate contract research organisation operating in the biotech space could be expected to take out.

EXECUTION

Executed by **iNGENu Pty Ltd (ACN 656 400 056)** in accordance with section 126 of the *Corporations Act 2001* (Cth), by its duly authorised agent:

[redacted] *Electronically signed by: Sud Agarwal Reason: I have reviewed this document Date: Mar 21, 2023 13:07 GMT+8*

Signature

Sud Agarwal

CEO 21-Mar-2023

Position (Print) Date

[redacted] *Electronically signed by: Darryl Davies Reason: I approve this document Date: Mar 21, 2023 12:33 GMT+8*

Name (Print)

Darryl Davies

COO 21-Mar-2023

Position (Print) Date

Executed by **Psyence Australia Pty Ltd (Company Number TBC)** in accordance with its constituent documents and the laws of its place of incorporation

[redacted] *Electronically signed by: Neil Maresky Reason: I approve this document Date: Mar 20, 2023 11:01 EDT*

Signature of Director

Neil Maresky

Name of Director (Print)

20-Mar-2023

Date

[redacted] *Electronically signed by: Warwick Corden-Lloyd Reason: I approve this document Date: Mar 20, 2023 16:53 GMT+2*

[redacted] *Electronically signed by: MG Pennisi Reason: I approve this document Date: Mar 21, 2023 07:25 GMT+10*

Signature of Director

Warwick Corden-Lloyd Mario Pennisi

Name of Director (Print)

20-Mar-2023 21-Mar-2023

Date Date

TERMS AND CONDITIONS

This Agreement is entered into between you and us (as defined in the Schedule), together the **Parties** and each a **Party**.

Background

A. We are a company offering contract research organisation services.

B. You are a pharmaceutical company which is sponsoring a clinical trial in Australia.

C. You have engaged us to provide the Services on the terms and conditions of this Agreement and an applicable Study Order.

1. Term

1.1 This Agreement will operate for the Term.

2. Services

2.1 In consideration of your payment of the Price, we will perform the relevant Services in accordance with this Agreement and the applicable Study Order, whether ourselves or through our Personnel.

2.2 We will provide the Services in accordance with this Agreement, as set out in the applicable Study Order.

2.3 Save as otherwise set out in a Study Plan and subject to the provisions of clauses 3.6, 3.7 and 4, you acknowledge and agree that any dates for delivery or for completion of the Services notified by us are estimates only, and we will have no Liability to you for failing to meet any delivery or milestone date. The foregoing shall not detract from our liability for penalties for delays as set out in the Study Order, nor reduce our liability under the provisions of clause 18.

2.4 We will commence the performance of the relevant Services within a reasonable time after the later of:

(a) the execution of the relevant Study Order under this Agreement; and

(b) the satisfaction of any other conditions precedent contemplated by the relevant Study Order.

2.5 You acknowledge and agree that where the scope, timing and cost of the Services are dependent on the acts and decision of third parties including Regulatory Authorities and Government Agencies:

(a) it is your responsibility to obtain all necessary approvals from the relevant Regulatory Authorities and Government Agencies, unless the Study Order expressly provides that any such tasks are our responsibility;

(b) we cannot guarantee any outcome or that any approval from a Regulatory Authority or Government Agency will be obtained;

(c) we have no control over, and are not responsible for, the decisions of any Regulatory Authority or Government Agencies;

(d) we are not responsible or liable for any changes to the scope, or timing or Price of the Services (including the termination or suspension of a Study) which occurs, or needs to occur, as the result of a decision by a Regulatory Authority or Government Agency; and

(e) any decision of a Regulatory Authority or Government Agency in relation to the Study Product or a Study may result in a Variation Event as set out in clause 4.3.

2.6 We will perform all Clinical Services in Australia.

2.7 Notwithstanding any other provision of this Agreement, we acknowledge and agree, and undertakes that we will not, claim the R&D Tax Incentive in respect of any Services provided in accordance with this Agreement or a Study Order.

3. Study Orders

3.1 This Agreement constitutes a “standing offer” under which, during the Term, you may engage us to conduct Services under separate Study Orders.

3.2 The details of each Study under this Agreement shall be documented in writing and set out in a Study Order. A form of Study Order is provided at Annexure 1 to this Agreement.

3.3 Each Study Order is subject to, and will be governed by, this Agreement and any other conditions agreed to by the Parties in writing. To the extent of any ambiguity or discrepancy between an Order and this Agreement, the terms of this Agreement will prevail.

3.4 We will only be required to comply with a Study Order if:

(a) both Parties have agreed to the terms of the relevant Study Order in writing; or

(b) the Parties have accepted the Study Order in accordance with the terms of the Study Order; or

(a) the Parties have agreed in writing to an amended Study Order.

3.5 Each Study Order is subject to, and will be governed by, this Agreement and any other conditions agreed to by the Parties in writing. To the extent of any ambiguity or discrepancy between an Order and this Agreement, the terms of this Agreement will prevail to the extent required to resolve the ambiguity or inconsistency, unless and to the extent the Study Order expresses an intention to take precedence on a particular issue.

3.6 We will carry out the Services as set out in the Study Order. to achieve the Deliverables by the date set against the same in the Study Plan, subject to the provisions of clause 4.

3.7 We shall at all times use our reasonable endeavors to minimize any delay in the performance of our obligations under each Study Order.

3.8 We acknowledge that the Services may be divided into stages and progression of each stage is dependent on notice to proceed to the next stage being furnished by you in writing. Accordingly, we will not commence any Services in respect of a stage of Services as set out in the Study Plan unless you have provided express written instructions to proceed with that stage. The Parties shall hold monthly review meetings, at a time and location to be agreed to discuss progress of the Services from stage to stage. You shall exercise this discretion in accordance with applicable laws and regulatory

compliance and approvals, taking patient risk and safety into account.

3.9 In addition to the monthly review meetings described at Clause 3.3, the Parties shall meet at, or shortly after, completion of each stage of the Services to discuss the results of that stage and to decide on whether to proceed to the next stage.

4. Variation

4.1 You may request a variation or change to the Services set out in a Study Order, including the timing for the supply of the Services (**Variation**), by providing written notice to us, with details of the Variation (**Variation Request**). We will not be obliged to comply with a Variation Request unless we accept the Variation Request in writing. The Parties agree to comply with this Agreement and the relevant Study Order as varied by any Variation Request accepted once agreed in writing, including any associated change to the Study Budget or Price.

4.2 If we reasonably consider that any instruction or direction from you constitutes a Variation, then we will not be obliged to comply with such instruction or direction unless a Variation Request has been issued and accepted by us in accordance with clause 4.1.

4.3 Where the Services are delayed, varied or changed, or the costs of providing the Services increases (**Variation Event**) and the cause of that Variation Event relates solely to, or is solely connected with:

(a) your failure to meet your obligations under this Agreement or a Study Order, or delays caused by you not providing us with the required information requested by us, or failing to sign or execute required documents, you agree to pay us our reasonable additional costs and expenses that we may incur as result of the Variation Event; or

(b) the acts or omissions of a third party, the decisions or recommendations of a Regulatory Authority or Government agency, or an event or circumstance beyond a Party's reasonable control,

then the Parties agree that:

i. where there is a delay, the delay will not constitute a breach of the applicable Study Order or the Agreement by either Party;

ii. we are entitled to stop providing the Services until the Parties have reached written agreement about new completion dates for the Services and any reasonable changes to the Price which are necessary in view of the delays; and

iii. if you instruct us to continue with the Services, you agree to be responsible for any additional costs incurred by us when performing the Services (including any additional Expenses).

4.4 All Variation Requests will be priced as reasonably determined by us.

4.5 No variation to this Agreement or a Study Order (including to the Services) will be effective unless agreed in writing by both Parties.

5. Your obligations

5.1 Prior to our commencement of the Services, you must:

(a) provide us with all current and relevant information regarding the Study Product, including but not limited to any applicable Certificate of Analysis, investigator's brochure, certificate of Good Manufacturing Practice and Medical Data Sheets, regarding the Study Product as reasonably required to justify the nature, scope and duration of the Study;

(b) provide us with any other information reasonably requested by us, in order for us to provide the Services and to ensure our Personnel are familiar with the appropriate use of the Study Product;

(c) obtain all relevant regulatory advice in relation to the Study Product; as determined in your discretion;

(d) enter into all necessary agreements with the Study Sites conducting the Study; and

(e) provide us with your authority to act on your behalf with the Study Sites clinical sites.

5.2 Unless stated otherwise in a Study Order, you are responsible for obtaining, and providing to us if necessary, any access, consents, licences, approvals and permissions from other parties necessary for the Services to be provided, at your cost.

6. Compliance with standards and guidelines

6.1 The Parties must (to the extent applicable) comply with the following:

(a) all applicable Laws and requirements of each relevant Regulatory Authority;

(b) 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 investigations, or other such regulations or guidance governing the conduct of clinical research in the jurisdiction of the Study;

(c) 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);

(d) the Guideline for Good Clinical Practice developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (**ICH**), being the version in force from time to time or its replacement;

(e) the procedures and practices described in ISO 14155:2011, being the version in force from time to time, or its replacement, of the International

Standard ISO14155:2011 'Clinical investigation of medical devices for human subjects – Good clinical practice' developed by the International Organisation for Standardisation; and

(f) the NHMRC Statement and any other relevant NHMRC publication or guideline that relates to clinical trials.

6.2 Where a Regulatory Authority or Government Agency, Study Site or Principal Investigator has made a decision to cease or suspend a Study due to safety reasons (including adverse events) **(Suspension Event**), you agree:

(a) to comply with all recommendations, decisions or instructions of the Relevant Regulatory Authority, Government Agency, Clinical Site or Principal Investigator;

(b) to bear all costs associated with the suspension or cessation of the Study; and

(c) that we are not liable and will have no responsibility for any costs or Liabilities you incur due to the cessation or suspension of a Study; and

(d) to pay any additional costs that we incur as a result of the suspension or cessation of a Study.,

subject to the provisions of clause 18 and clause 6.3.

6.3 Subclauses (b), (c) and (d) of clause 6.2 do not apply where the Suspension Event is directly connected with the fraudulent, negligent or wilful acts or omissions, or material breach of this Agreement, by us (provided any such breach is not due in whole or in part to your acts or omissions or an event or the acts of a third party outside our control).

7. Relationship of the Parties

7.1 Both Parties are independent contractors. Nothing in this Agreement constitutes, or will be deemed to constitute, a relationship of employer and employee between the Parties, a partnership between the Parties or make any Party the agent of the other Party for any purpose.

7.2 Subject to any express provision in this Agreement to the contrary, neither Party has any right or authority to and must not do any act, enter into any contract, make any representation, give any warranty, incur any liability, assume any obligation, whether express or implied, of any kind on behalf of the other Party or bind the other Party in any way.

8. Reporting Requirements

8.1 You must monitor the use of the Study Product in other clinical trials and studies and notify us immediately if a clinical trial (using the Study Product) has been terminated or suspended or the Study Product recalled in any jurisdiction.

8.2 A Party must notify the other Party of any events:

(a) which may require alteration of the conduct of a Study;

(b) which may affect the rights, interests, safety or well-being of Study Participants; or

(c) which it is required to report to the TGA, Reviewing HREC or other regulatory body or authority under the NHMRC Safety Monitoring Guidance or the NHMRC Reporting of Serious Breaches Guidance.

8.3 The Parties must work together to notify all relevant Regulatory Authorities of the events that the Sponsor is required to report under the NHMRC Safety Monitoring Guidance or the NHMRC Reporting of Serious Breaches Guidance within the time periods specified in the NHMRC Safety Monitoring Guidance and the NHMRC Reporting of Serious Breaches Guidance.

8.4 You must cooperate with us and/or Reviewing HREC in investigating any event that is required to be reported to the Reviewing HREC arising out of or in connection with a Study.

8.5 If a Party receives any correspondence or inquiry from a Regulatory Authority or Government Agency in relation to a Study, it must, to the extent permitted by law:

(a) promptly notify the other Party in writing, and in any event no later than 24 hours after receiving the correspondence or being made aware of the inquiry; and

(b) forward to the other Party copies of any correspondence from any Regulatory Authority or Government Agency relating to any Study.

8.6 Each Party acknowledges that it may not direct the manner in which the other Party fulfils its obligations to permit inspection by government entities, however where possible, we will all ow your Personnel to be present at such inspections.

9. Premises

9.1 In the event that we are required to attend your Premises to provide the Services to you, you agree to provide us (and our Personnel) with reasonable access to the Premises (and the facilities at the Premises), and any other premises reasonably necessary for us to perform the Services, free from harm or risk to health or safety:

(a) at the times and on the dates agreed with you; and/or

(b) to enable us to comply with our obligations under this Agreement or at Law,

and you agree to pay us any reasonable and documented additional costs that we may suffer or incur if you fail to do so, as per the date of the invoice to which the Services relate, but subject to our provision to you of an invoice setting out the same.

10. Exclusivity, Restraint & Non-Circumvention

10.1 You (whether inadvertently, directly or indirectly), must not, during the Term of the Agreement and for a period of 3 months after the termination of the Agreement (Restraint Period):

(a) induce or solicit our or any of our Personnel (who were Personnel at the date of termination or expiry of this Agreement or within the 12 months prior), to leave their employment, agency or contractual arrangement with us; or

compete with us or any of our Group Companies.

10.2 The non-compete set out in clause 10.10shall not apply in respect of any business or ventures in which you or any of your group companies are involved as at the Commencement Date, or planned business or ventures which have been disclosed to us as at the Commencement Date.

10.3 For the duration of the Term, we shall not provide services substantially similar (same indication (palliative care) and the same IMP (psilocybin)) to the Services to any direct competitor yours in the psychedelics industry.

11. Insurance

11.1 The Parties will procure and maintain in full force and effect the Required Insurance.

11.2 Where you are required to obtain clinical trial insurance cover for a Study (either under any applicable Law or as specified in this Agreement), you must ensure that we are named as an insured party under your insurance policy, with respect to the activities including conduct of the Study and the indemnity obligations under this Agreement.

11.3 You must provide us with evidence of insurance by way of a certificate of currency, as requested by us from time to time.

12. Payment

12.1 In consideration for us providing the Services, you agree to pay us the Price and any Pass Through Costs in accordance with this Agreement and the relevant Study Order.

12.2 We will issue you with an invoice which will:

(a) be issued in Australian dollars (or such other currently as agreed in writing between the Parties);

(b) include our bank and account details to enable EFT payment;

(c) sufficiently describe the Services to which the invoice relates;

(d) include any and all Expenses and Pass Through Costs incurred during the invoicing period;

(e) be in the form of a valid tax invoice and clearly and separately show the amount of any GST payable, if applicable; and

(f) be issued in accordance with the terms of the Study Order; and

12.3 You must pay each undisputed invoice issued by us according to the Payment Terms.

12.4 If any payment has not been made in accordance with the Payment Terms, we may (at our absolute discretion), after a period of 30 days, suspend provision of the Services.

13. Study Product

13.1 You must supply us or the Study Site (as specified in a Study Order) with such quantities of the Study Product as will be required for the purpose of the Study. You must ensure that all supplied Study Product will be packaged in safe and appropriately labelled containers. You will at all times remain the owner of the Study Product.

13.2 If specified in a Study Order, on termination or expiry of this Agreement, we must promptly return any unused Study Product to you, or under your guidance appropriately destroy expired and / or unused product.

14. Warranties and Representations

14.1 Each Party represents, warrants and agrees that:

(a) it will comply with this Agreement and all applicable Laws;

(b) that all information and documentation that it provides to the other Party in connection with this Agreement is true, correct and complete as at the date of provision;

(c) that no Insolvency Event has occurred in respect of it and that it will immediately notify the other Party if it is (or is likely to be) the subject of an Insolvency Event;

(d) it has full legal capacity, right, authority and power to enter into this Agreement, to perform its obligations under this Agreement, and to carry on its business;

(e) that this Agreement constitutes a legal, valid and binding agreement, enforceable in accordance with its terms;

(f) if applicable, it holds a valid ABN which has been advised to the other Party; and

(g) if applicable, it is registered for GST purposes.

14.2 You represent, warrant and agree:

(a) that, to the best of your knowledge and belief, the Study Product, and all information and documents that you provide to us do not infringe any third party rights (including any Intellectual Property Rights);

(b) to comply with our reasonable requests or requirements;

(c) that you (and to the extent applicable, your Personnel) will provide us with all documentation, information, instructions, cooperation and access reasonably necessary to enable us to provide the Services;

(d) that you have not relied on any representations or warranties made by us in relation to the Services (including as to whether the Services are or will be fit or suitable for any particular purposes), unless expressly stipulated in this Agreement or a Study Order;

(e) that any information, advice, material, work and services (including the Services) provided by us under this Agreement does not constitute legal, financial, merger, due diligence or risk management advice; and

(f) that you will be responsible for the use of any part of the Services, and you must ensure that no person uses any part of the Services:

(1) to break any Law or infringe any person's rights (including Intellectual Property Rights);

(2) to transmit, publish or communicate material that is defamatory, offensive, abusive, indecent, menacing or unwanted; or

(3) in any way that damages, interferes with or interrupts the supply of the Services.

14.3 Neither Party gives any warranty that the Study outcomes will be achieved or that outcomes will be commerciality valuable, patentable, reliable safe or fit for purpose.

15. Intellectual Property

15.1 As between the Parties:

(a) we own all Intellectual Property Rights in Our Materials;

(b) you own all Intellectual Property Rights in Your Materials; and

(c) nothing in this Agreement constitutes a transfer or assignment of any Intellectual Property Rights in Our Materials or Your Materials.

15.2 Unless otherwise specified in a Study Order, as between the Parties, ownership of all Intellectual Property Rights in any New Materials or Improvements will vest in you upon immediately upon creation. We will ensure that any subcontract or third party agreement we are a party to in connection with a Study or performance of the Services provides that any such Intellectual Property Rights will immediately upon creation vest in you. If, notwithstanding the foregoing, any Intellectual Property Rights in any Deliverable, Improvement or New Material vests in us, we agree to assign and hereby do assign all such rights to you. We agree to execute all documents and do all acts necessary or desirable to assign and transfer to you any and all rights in such Deliverable, New Materials and / or Improvements so as to assure your full, unrestricted title to such Intellectual Property Rights and to give effect to the intention of this clause. Furthermore we undertake to do all things and sign all such documents as may be required to register such New Materials and Improvements in patent applications or similar forms of registered intellectual property protection or to prove or establish your title to such New Materials and Improvements.

15.3 Each Party grants to the other Party a royalty-free, non-exclusive, worldwide licence to use its Intellectual Property to the extent necessary for us to provide, and you to obtain the full benefit of, the Services. In respect of the licence granted by you to us, that licence is limited in purpose and granted solely for the purposes and during the term of this Agreement.

15.4 You grant us a non-exclusive, revocable, worldwide, non-sublicensable and non-transferable right and licence, to use Your Materials that you provide to us, the New Materials and Improvements, for the limited purpose of our performance of our obligations under this Agreement. Any and all rights of use and licence under this clause shall terminate on completion of the Study.

15.5 We grant you a non-exclusive, revocable, worldwide, non-sublicensable and non-transferable right and licence, for the duration of the Term, to use Our Materials that we provide to you solely for your use and enjoyment of the Services, as contemplated by this Agreement. To the extent that any part of Our Materials forms part of any New Materials or Improvements or commercialisation of use of the New Materials or Improvements is reliant on Our Materials, we hereby grant to you an irrevocable, perpetual, fully paid up, transferable sublicensable, worldwide license, to use Our Materials strictly to exploit the Deliverables, New Materials or Improvements.

15.6 We warrant that any licence granted under this Agreement to you and the exercise of any such licence and / or the Deliverables, New Materials and/or the Improvements will not infringe on the intellectual property rights of any third party.

15.7 If a Party (or its Personnel) has any Moral Rights in any material provided, used or prepared in connection with this Agreement or the provision of the Services, that Party will (and will procure that its Personnel) consent to the other Party's use or infringement of those Moral Rights in accordance with this Agreement.

16. Confidential Information

16.1 Each Receiving Party agrees:

(a) not to disclose the Confidential Information of the Disclosing Party (or its Group Companies) to any third party;

(b) to use all reasonable endeavours to protect the Confidential Information of the Disclosing Party from any unauthorised disclosure; and

(c) to only use the Confidential Information of the Disclosing Party for the purposes for which it was disclosed or provided by the Disclosing Party, and not for any other purpose.

16.2 Deliverables, New Materials and Improvements are Confidential Information of you.

16.3 The obligations in clause 16.1 do not apply to Confidential Information that:

(a) is required to be disclosed in order for the Parties to comply with their obligations under this Agreement;

(b) is authorised to be disclosed by the Disclosing Party;

(c) is in the public domain and/or is no longer confidential, except as a result of a breach of this Agreement; or

(d) must be disclosed by Law or by a Regulatory Authority, including under subpoena.

16.4 Any disclosure of the Confidential Information permitted under clause 16.3 does not affect the confidential status of such Confidential Information and in any other circumstance such Confidential Information remains subject to the non-use and non-disclosure restrictions provided in this clause 16.

16.5 The Parties may retain Confidential Information:

(a) if they are required to do so by Law or by a Regulatory Authority;

(b) contained in board papers or board minutes of the relevant Party (to the extent those documents contain only the level of detail consistent with normal practices);

(c) contained in working papers which the relevant Party is required to retain for insurance or risk management purposes, or to comply with any

professional standards applicable to the relevant Party (to the extent those documents contain only the level of detail consistent with normal practices);

(d) contained in any advice or report which is prepared by an adviser of the Party for the purpose; and

(e) that is stored electronically on back-up servers under an existing routine data back-up process, if:

i. that Confidential Information is deleted from local hard drives and local media; and

ii. no attempt is made to recover it from those servers, unless required by Law or any applicable professional standards.

Any Confidential Information retained under this clause 16.5 remains subject to this Agreement.

16.6 Each Party agrees that monetary damages may not be an adequate remedy for a breach of this clause 16 (Confidential Information). A Party is entitled to seek an injunction, or any other remedy available at law or in equity, at its discretion, to protect itself from a breach (or continuing breach) of this clause 16 (Confidential Information).

17. Privacy

17.1 Each Party must comply with and do all things requested by the other (acting reasonably) to enable each Party to comply with all applicable Privacy Laws.

17.2 Without prejudice to the generality of clause 17.1, each Party must, in relation to any Personal Information processed in connection with the performance by it of its obligations under this Agreement:

(a) take reasonable steps to protect the information from misuse, interference, loss, unauthorised access, modification and disclosure;

(b) where any personal information is disclosed by one Party to the other, ensure that the disclosing party has obtained all necessary consents and authorisations from the individual to whom the personal information relates and comply with all relevant Privacy Laws which apply to it; and

(c) comply with any additional obligations which the receiving Party is obliged to impose from time to time in order to ensure compliance by it with any relevant Privacy Laws.

17.3 Study Personal Information

(a) The Parties acknowledge and agree that information collected in respect of a Study may include Personal Information and sensitive Personal Information which is subject to specific legislation relating to the processing, storage, transfer and use of such data.

(b) For the purposes of this clause:

(i) we will comply with all applicable Laws and regulations relating to the protection and use of Personal Information and data privacy in our conduct and reporting of the Study;

(ii) we will take all reasonable technical and organisational measures to prevent unauthorised or unlawful processing, accidental loss, destruction of, damage to, or disclosure of such information; and

17.4 Each Party agrees to comply with the legal requirements of the Australian Privacy Principles as set out in the Privacy Act (as if it were an "APP entity" as defined in the Privacy Act) and any other applicable Privacy Laws that may apply to either of us, the Services and / or the Deliverables. Each Party must not (and procure its Personnel do not) do anything which may cause the other Party to be in breach of any Privacy Laws.

17.5 In respect of any Personal Information (including in respect of our clients and employees) that you receive or have access to in connection with this Agreement, you must (and procure your Personnel must):

(a) only use the Personal Information in accordance with our instructions and for the sole purpose of providing the Services; and

(b) keep the Personal Information secure and protect it from loss, damage and unauthorised use or disclosure.

17.6 In respect of any Security Incident, each Party must (and procure its Personnel must):

(a) notify the other Party within 2 Business Days of becoming aware of the Security Incident;

(b) comply with its obligations under the Privacy Laws;

(c) provide the other Party with all information it reasonably requests;

(d) assist and fully cooperate with the other Party, at the cost of the Party experiencing a Security Incident, in investigating and remedying the Security Incident; and

(e) take any other action, at cost of the Party experiencing a Security Incident, that other Party reasonably deems necessary in connection with the Security Incident.

17.7 You will take appropriate measures to protect the confidentiality and security of all Personal Information that you receive from us in respect of each Study and comply with all applicable Laws and regulations relating to the protection and use of Personal Information and data privacy.

18. Limitations on liability and Indemnity

18.1 Despite anything to the contrary, to the maximum extent permitted by law, each Party (**Indemnifying Party**) indemnifies the other, its Personnel and any of their Group Companies (the **Indemnified**), and hold the Indemnified harmless, from and against any Liability suffered or incurred by the Indemnified, arising from, or in connection with, any:

(a) fraudulent, negligent or wrongful act or omission of the Indemnifying Party or any of its Personnel;

(b) breach by a Party or any of its Personnel of any warranty under clause 14 (Warranties and Representations);

(c) property loss or damage or personal injury (including death) caused by the Indemnifying Party or any of its Personnel; and

(d) breach of this Agreement.

18.2 Despite anything to the contrary, to the maximum extent permitted by law:

(a) neither Party will be liable for Consequential Loss;

(b) a Party's liability for any Liability under this Agreement will be reduced proportionately to the extent the relevant Liability was caused or contributed to by the acts or omissions of the other Party (or any of its Personnel), including any failure by that other Party to mitigate its loss;

(c) we will not be liable for any claims made by a Study Participant in connection with or arising from the conduct of the Study, except to the extent the relevant Liability was caused by our fraudulent actions, gross negligence or willful misconduct; and

(d) each Party's aggregate liability for any Liability arising from or in connection with this Agreement will be limited to 100% of the Price payable under the relevant Study Order to which the Liability relates the Price payable under the relevant Study Order to which the Liability relates.

18.3 The limitation of liability provisions in this clause do not apply to any tangible property damage, breach of confidentiality, personal injury, illness or death or to any Loss, Claim or Liability arising from a Party's fraud, gross negligence or wilful misconduct.

19. Termination

19.1 Either Party may terminate this Agreement in writing by giving the other Party 30 days' notice if there are no current Study Orders in force.

19.2 Either Party may terminate this Agreement, with immediate effect by providing written notice to the other Party (Defaulting Party) if:

(a) the Defaulting Party is in breach of this Agreement and such breach is incapable of being remedied;

(b) the Defaulting Party is in breach of this Agreement and such breach is capable of being remedied, but the Defaulting Party fails to remedy the breach within thirty (30) days of its receipt of a notice requiring it to do so;

(c) the Defaulting Party is persistently in breach of this Agreement;

(d) the Defaulting Party or the Defaulting Party's Personnel act or omit to act in a manner calculated or likely to bring the other Party into disrepute;

(e) the Defaulting Party is subject to an Insolvency Event; or

(f) the Defaulting Party undergoes a change of Control (provided, in the case of the Sponsor, it shall not constitute a default if the CRO is provided with notice of the change of Control within 30 days following its occurrence, and the CRO's responsibilities under this Agreement do not change because of such change of Control).

19.3 You will be entitled to terminate this Agreement and / or any Study Order then in force immediately by written notice in the event that you have failed to secure sufficient funding to finance an entire Study per the Study Order by the date upon which the first patient dosing is scheduled to occur in terms of the Study Plan.

19.4 The Agreement or a Study Order may be terminated by a Party before the end of the Term by written notice to the other Party with immediate effect if the Study detailed in the Study Order is not continuing for reasons including:

(a) the Study Product has given rise to unacceptable or serious adverse events;

(b) the Study Product is being shown not to be effective;

(c) the Study Product has been demonstrated to be effective and the Sponsor has determined that further testing is not required; or

(d) a Regulatory Authority requires the suspension or cessation of the study.

19.5 Upon expiry or termination of this Agreement or a Study Order, or a direction to suspend Services for more than 90 days:

(a) We will cease providing the Services under the relevant Study Order(s);

(b) if required, the Parties will discuss and coordinate the termination or suspension (as the case may be) of any relevant Study to ensure compliance with Law, participant safety and, if possible and necessary or desirable or where required by any applicable Laws, provide continuity of treatment in a safe and efficient manner;

(a) you will pay for:

i. all undisputed invoices due and payable at the effective date of termination;

ii. all Services properly provided under this Agreement or a Study Order prior to termination, including or suspension (as the case may be),

iii. all Services which have been properly provided under this Agreement or a Study Order and have not yet been invoiced to you, and where your obligation to pay is linked to a milestone set out in an applicable Study Order and the invoice was due to be issued upon completion of the milestone, you agree that you will pay for all Services properly provided towards that milestone until the date of termination, irrespective of whether the milestone was completed or not; and

(c) all other amounts due and payable under this Agreement;

(d) you must also pay us any additional costs, Expenses and Pass Through Costs, reasonably and actually incurred, and which arise directly from such up to the effective date of termination, except where we are the Defaulting Party;

(e) you agree to promptly return (where possible), or delete or destroy (where not possible to return),

including any information, documentation or material owned by us that is in your possession or control, non-cancellable costs, subject to in all cases to our duty to use our reasonable endeavours to mitigate any rights you may have to any Intellectual Property in accordance with clause 15 (Intellectual Property) such additional costs following notice of termination); and

(f) we agree to promptly return (where possible), or delete or destroy (where not possible to return), any information, documentation or material owned by you that is in our possession or control.

19.6 We will retain your documents (including copies) as required by law or regulatory requirements. Your express or implied agreement to this Agreement constitutes your authority for us to retain or destroy documents in accordance with the statutory periods, or on expiry or termination of this Agreement.

19.7 Termination of this Agreement will not affect any rights or liabilities that a Party has accrued under it.

20. GST

20.1 If GST is payable on any supply made under this Agreement, the recipient of the supply must pay an amount equal to the GST payable on the supply. That amount must be paid at the same time that the consideration is to be provided under this Agreement and must be paid in addition to the consideration expressed elsewhere in this Agreement, unless it is expressed to be inclusive of GST. The recipient is not required to pay any GST until the supplier issues a tax invoice for the supply.

20.2 If an adjustment event arises in respect of any supply made under this Agreement, a corresponding adjustment must be made between the supplier and the recipient in respect of any amount paid by the recipient under this clause, an adjustment note issued if required, and any payments to give effect to the adjustment must be made.

20.3 If the recipient is required under this Agreement to pay for or reimburse an expense or outgoing of the supplier, or is required to make a payment under an indemnity in respect of an expense or outgoing of the supplier, the amount to be paid by the recipient is to be reduced by the amount of any input tax credit in respect of that expense or outgoing that the supplier is entitled to.

20.4 The terms “adjustment event”, “consideration”, “GST”, “input tax credit”, “recipient”, “supplier”, “supply”, “taxable supply” and “tax invoice” each has the meaning which it is given in the A New Tax System (Goods and Services Tax) Act 1999 (Cth).

21. General

21.1 **Email**: You agree that we are able to send electronic mail to you and receive electronic mail from you. To the maximum extent permitted by law, and subject to our obligation to ensure that we keep an maintain security systems and procedures which are industry standard or better, you release us from any Liability you may have as a result of any unauthorised copying, recording, reading or interference with that document or information after transmission, for any delay or non-delivery of any document or information and for any damage caused to your system or any files by a transfer.

21.2 **Amendment**: This Agreement may only be amended by written instrument executed by the Parties.

21.3 **Assignment**: Subject to clause 21.4 (Assignment of Debt), a Party must not assign or deal with the whole or any part of its rights or obligations under this Agreement without the prior written consent of the other Party (such consent is not to be unreasonably withheld), except in the case of a sale of all or substantially all of your business or assets (in which case consent is deemed to be granted).

21.4 **Assignment of Debt:** You agree that we may assign or transfer any debt owed by you to us, arising under or in connection with this Agreement, to a debt collector, or debt collection agency.

21.5 **Counterparts:** This Agreement may be executed in any number of counterparts that together will form one instrument.

21.6 Electronic execution: This Agreement may be executed electronically, including by means of such third-party online document execution service as we nominate**,** subject to such execution being in accordance with the applicable terms and conditions of that document execution service.

21.7 **Disputes**: If any dispute or claim (including any question regarding its existence, validity or termination) arises out of or in connection with this Agreement (Dispute), either Party may issue a notice to the other Party outlining the dispute or claim (Notice of Dispute). Within 14 days of a Notice of Dispute, senior representatives of the Parties must meet in good faith to resolve the Dispute by negotiation or such other means as they mutually agree. If the Parties cannot agree how to resolve the Dispute at that initial meeting, either Party may:

(a) where the Parties are both located in Australia, refer the matter to a mediator. If the Parties cannot agree on who the mediator should be, either Party may ask the Law Institute of Victoria to appoint a mediator. The mediator will decide the time, place and rules for mediation. The Parties agree to attend the mediation in good faith, to seek to resolve the Dispute. The costs of the mediation will be shared equally between the Parties; and

(b) where either Party is located outside of Australia, refer the matter to arbitration administered by the Australian Centre for International Commercial Arbitration (ACICA), with such arbitration to be conducted in Melbourne, Victoria, in English and in accordance with the ACICA Arbitration Rules. The costs of the arbitration will be shared equally between the Parties and the determination of the arbitrator will be final and binding.

21.8 The Parties must seek to resolve the Dispute by way of Alternative Dispute Resolution Methods prior to issuing proceedings.

Nothing in this clause will operate to prevent a Party from seeking urgent injunctive or equitable relief from a court of appropriate jurisdiction.

21.9 **Entire agreement**: Subject to your Consumer Law Rights, this Agreement (including any Schedules and Annexures) together with each Study Order contains the entire understanding between the Parties in relation to their subject matter and the Parties agree that no representation or statement has been made to, or relied upon by, either of the Parties, except as expressly stipulated in this Agreement, and this or a Study Order. This Agreement and each Study Order supersedes all previous discussions, communications, negotiations, understandings, representations, warranties, commitments and agreements, in respect of their subject matter.

21.10 **Further assurance:** Each Party must promptly do all things and execute all further instruments necessary to give full force and effect to this Agreement and their obligations under it.

21.11 **Force Majeure**: Neither Party will be liable for any delay or failure to perform their respective obligations under this Agreement if such delay or failure is due to any circumstance beyond its reasonable control, including where such delay and failure is caused or contributed to by a Force Majeure Event. In the case of a Force Majeure Event, the Party which is unable to perform its obligations must provide written notice to the other Party setting out the nature of the Force Majeure Event and the expected duration. The affected obligations will be suspended for the duration of the Force Majeure Event. If the Force Majeure Event continues for a period of longer than three (3) months, either Party may terminate this Agreement. This clause will not apply to a Party's obligation to pay any amount that is due and payable to the other Party under this Agreement.

21.12 **Governing law**: This Agreement is governed by the laws of Victoria, Australia. Each Party irrevocably and unconditionally submits to the exclusive jurisdiction of the courts operating in Victoria, Australia and any courts entitled to hear appeals from those courts and waives any right to object to proceedings being brought in those courts.

21.13 **Notices**: Any notice given under this Agreement must be in writing addressed to the relevant address last notified by the recipient to the Parties. Any notice may be sent by standard post or email, and will be deemed to have been served on the expiry of 48 hours in the case of post, sent within one country, or 5 Business Days if sent internationally, or at the time of transmission in the case of transmission by email if sent before 5.00pm on a Business Day, otherwise the following Business Day.

21.14 **Relationship of Parties**: This Agreement is not intended to create a partnership, joint venture, employment or agency relationship between the Parties.

21.15 **Severance**: If a provision of this Agreement is held to be void, invalid, illegal or unenforceable, that provision is to be read down as narrowly as necessary to allow it to be valid or enforceable, failing which, that provision (or that part of that provision) will be severed from this Agreement without affecting the validity or enforceability of the remainder of that provision or the other provisions in this Agreement.

21.16 **Survival:** Without limiting the clauses which by their nature survive termination of this agreement, clauses 15 (Intellectual Property), 16 (Confidential Information), 18 (Privacy), 21 (Limitations on liability and Indemnity),and 19 (Termination) and 22 (Definitions) and 23 (Interpretation) will survive termination or expiry of this Agreement.

22. Definitions

In this Agreement, unless the context otherwise requires, capitalised terms have the meanings given to them in the Schedule, and:

Affiliate means any company which (directly or indirectly) controls, or is controlled by or is under common control with a Party.

Agreement means this "Contract Research Organisation Master Service Agreement" attachments, annexures or schedules.

Alternative Dispute Resolution Methods means mediation or arbitration.

Assumptions means the "Assumptions" and "Project Dependencies" as set out in the relevant Study Order issued under it and any documents attached to, or referred to in, each of them.

Business Day means a day on which banks are open for general banking business in Victoria, excluding Saturdays, Sundays and public holidays.

Claim means any third party claim, allegation, cause of action, proceeding, demand, debt, liability, obligation, cost or expense of any nature however it arises and whether it is present or future, fixed or unascertained, actual or contingent (whether or not the facts, matters or circumstances giving rise to that claim are known to that person or to any other person at the date of this Agreement) and whether at law, in equity, under statute or otherwise.

Confidential Information includes information which:

(a) is disclosed to the Receiving Party in connection with this Agreement at any time;

(b) is prepared or produced under or in connection with this Agreement at any time;

(c) relates to the Disclosing Party's (or its Group Company's) business, assets or affairs; or

(d) relates to the subject matter of, the terms of and/or any transactions contemplated by this Agreement,

whether or not such information or documentation is reduced to a tangible form or marked in writing as "confidential", and howsoever the Receiving Party receives that information.

Consequential Loss includes any consequential loss, indirect loss, real or anticipated loss of profit, loss of benefit, loss of revenue, loss of business, loss of goodwill, loss of opportunity, loss of savings, loss of reputation, loss of use and/or loss or corruption of data, whether under statute, contract, equity, tort (including negligence), indemnity or

otherwise. The Parties acknowledge and agree that your obligation to pay us the Price and any other amounts due and payable by you to us under this Agreement will not constitute "Consequential Loss" for the purposes of this definition.

Control has the meaning given in section 50AA of the *Corporations Act 2001* (Cth) except that in addition an entity controls a second entity if:

(a) the first entity would be taken to control the second entity but for subsection 50AA(4); or

(b) the first entity has voting power (as defined in section 610 of the Corporations Act) of at least 50% in the second entity.

CRO means contract research organisation.

Deliverables means any materials, goods, items or other deliverables forming part of the Services, as particularised in the Study Order.

Disclosing Party means the party disclosing Confidential Information to the Receiving Party.

Dispute has the meaning given in clause 21.7.

Equipment means the equipment supplied to the CRO by or on behalf of the Sponsor for the purposes of the Study, including that specified in the Study Order.

Force Majeure Event means any event or circumstance which is beyond a Party's reasonable control including but not limited to, acts of God including fire, hurricane, typhoon, earthquake, landslide, tsunami, mudslide or other catastrophic natural disaster, civil riot, civil rebellion, revolution, terrorism, insurrection, militarily usurped power, act of sabotage, act of a public enemy, war (whether declared or not) or other like hostilities, ionising radiation, contamination by radioactivity, nuclear, chemical or biological contamination, any widespread illness, quarantine or government sanctioned ordinance or shutdown, pandemic (including COVID-19 and any variations or mutations to this disease or illness) or epidemic.

Government Agency means:

(a) a government or government department or other body;

(b) a governmental, semi-governmental or judicial person including a statutory corporation; or

(c) a person (whether autonomous or not) who is charged with the administration of a law.

Group Company means us and our "related bodies corporate" as that term is defined under the Corporations Act 2001 (Cth).

HREC means a Human Research Ethics Committee registered with the National Health and Medical Research Council.

Improvements means any development, modification, adaptation or improvement of Your Materials or any New Materials made by or on behalf of either Party (or any of their respective Personnel), or in respect of which Intellectual Property Rights are acquired by, either Party during the Term.

Insolvency Event means any of the following events or any analogous event:

(a) a Party disposes of the whole or any part of the Party's assets, operations or business other than in the ordinary course of business;

(b) a Party ceases, or threatens to cease, carrying on business;

(c) a Party is unable to pay the Party's debts as the debts fall due;

(d) any step is taken by a mortgagee to take possession or dispose of the whole or any part of the Party's assets, operations or business;

(e) any step is taken for a party to enter into any arrangement or compromise with, or assignment for the benefit of, a Party's creditors or any class of a Party's creditors; or

(f) any step is taken to appoint an administrator, receiver, receiver and manager, trustee, provisional liquidator or liquidator of the whole or any part of a Party's assets, operations or business.

Intellectual Property means any copyright, registered or unregistered designs, patents or trade marks, domain names, know-how, inventions, processes, trade secrets or Confidential Information, circuit layouts, software, computer programs, databases or source codes, including any application, or right to apply, for registration of, and any improvements, enhancements or modifications of, the foregoing.

Intellectual Property Rights means for the duration of the rights in any part of the world, any industrial or intellectual property rights, whether registrable or not, including in respect of Intellectual Property.

Laws means all applicable laws, regulations, codes, guidelines, policies, protocols, consents, approvals, permits and licences, and any requirements or directions given by any government or similar authority with the power to bind or impose obligations on the relevant Party in connection with this Agreement or the supply of the Services.

Liability means any expense, cost, liability, loss, damage, claim, notice, entitlement, investigation, demand, proceeding or judgment (whether under statute, contract, equity, tort (including negligence), indemnity or otherwise), howsoever arising, whether direct or indirect and/or whether present, unascertained, future or contingent and whether involving a third party or a Party to this Agreement or otherwise.

Loss means any damage, punitive damages, liability, Claim, obligation, duty, loss, charge, cost or expense (including legal expenses on a full indemnity basis and consultant's fees), interest, penalty, fine and tax, however it arises and whether it is present or future, fixed or unascertained, actual or contingent.

New Materials means all Intellectual Property developed, or created by or on behalf of us or you or any of your or our respective Personnel in connection with this Agreement or the supply of the Services, whether before or after the date

of this Agreement, but excludes Our Materials and Your Materials.

NHMRC means the National Health and Medical Research Council.

NHMRC Reporting of Serious Breaches Guidance means the NHMRC publication titled Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018) or its replacement.

NHMRC Safety Monitoring Guidance means the NHMRC publication titled Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) or its replacement.

NHMRC Statement means the NHMRC National Statement on Ethical Conduct in Human Research (2007) or its replacement.

Our Materials means all work, models, processes, technologies, strategies, materials, information, documentation and services that we may provide to you under this Agreement for use in the Study (whether before or after the date of the Agreement), and which may contain material which is owned by or licensed to us, and is protected by Australian and international laws.

Personnel means, in respect of a Party, any of its employees, consultants, suppliers, subcontractors or agents, but in respect of you, does not include us.

Personal Information means 'personal information' as defined in the Privacy Act.

Price means the price set out in a Study Order for the performance of the Services set out in that Study Order and includes any Deposit.

Privacy Act means the *Privacy Act 1988* (Cth).

Privacy Laws means the Australian Privacy Principles set out in the *Privacy Act 1988* (Cth) and any other privacy or anti-spam Laws applicable to you

R&D Tax Incentive means the 'research and development tax incentive' as set out in Division 355 of *the Income Tax Assessment Act 1997* (Cth) (as amended, superseded or replaced from time to time).

Receiving Party means the party receiving Confidential Information from the Disclosing Party.

Regulatory Authority means any body which has jurisdiction over the conduct of the Study and includes the TGA, Reviewing HREC and any overseas regulatory authorities or Government Agency who may audit or require to be audited any part of the Study including any safety review committees.

Required Insurance has the meaning set out in the Schedule or the TORO Document as applicable.

Reviewing HREC means the applicable Human Research Ethics Committee reviewing the Study.

Schedule means the schedule to this Agreement.

Security Incident means the actual or likely occurrence of any of the following in respect of the Personal Information:

(a) a breach of clause 17 (Privacy);

(b) an 'eligible data breach' (as that term is defined in the Privacy Act) caused or contributed by a Party or its Personnel.

Services means the services and the conduct of a Study as specified in the Study Order and further particularised in the relevant TORO Document (where applicable).

Study means an Australian clinical trial as specified in the Study Order.

Study Budget if required to be managed by the CRO, means the proposed budget for the Services to be conducted, and Expenses and Pass Through Costs to be incurred, under a Study Order, as set out in the Study Order.

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

Study Plan means, in relation to a Study Order, the section of the Study Order setting out the detailed Study implementation schedule for each stage of the Services including a detailed description of services and Deliverables per stage and a delivery date of each Deliverable.

Study Product means the active pharmaceutical ingredient, medicine or device being trialed or tested in a Study, as set out in the Study Order, and includes where relevant any placebo.

Study Site means the sites where a Study will be conducted.

Study Order means an order for the supply of the Services, issued by us in accordance with clause 3 (Study Orders), a form of which is provided at Annexure 1 to this Agreement.

TGA means the Therapeutic Goods Administration of the Commonwealth of Australia or any successor body.

TORO Document means the transfer of regulatory obligations document at Attachment 2.

Variation has the meaning given in clause 4 (Variation).

Your Materials means all work, models, processes, technologies, strategies, materials, information, documentation and services (including Intellectual Property), owned or licensed by you or your Personnel before the Commencement Date and/or developed by or on behalf of you or your Personnel independently of this Agreement.

23. Interpretation

In this Agreement, unless the context otherwise requires:

(a) a reference to this Agreement or any other document includes the document, all schedules and all annexures as novated, amended, supplemented, varied or replaced from time to time;

(b) a reference to any legislation or law includes subordinate legislation or law and all amendments, consolidations, replacements or re-enactments from time to time;

(c) a reference to a natural person includes a body corporate, partnership, joint venture, association, government or statutory body or authority or other legal entity and vice versa;

(d) no clause will be interpreted to the disadvantage of a Party merely because that Party drafted the clause or would otherwise benefit from it;

(e) a reference to a party (including a Party) to a document includes that party's executors, administrators, successors, permitted assigns and persons substituted by novation from time to time;

(f) a reference to a covenant, obligation or agreement of two or more persons binds or benefits them jointly and severally;

(g) a reference to time is to local time Victoria; and

(h) a reference to $ or dollars refers to the currency of Australia from time to time.

Psyence MSA

Final Audit Report 2023-03-21

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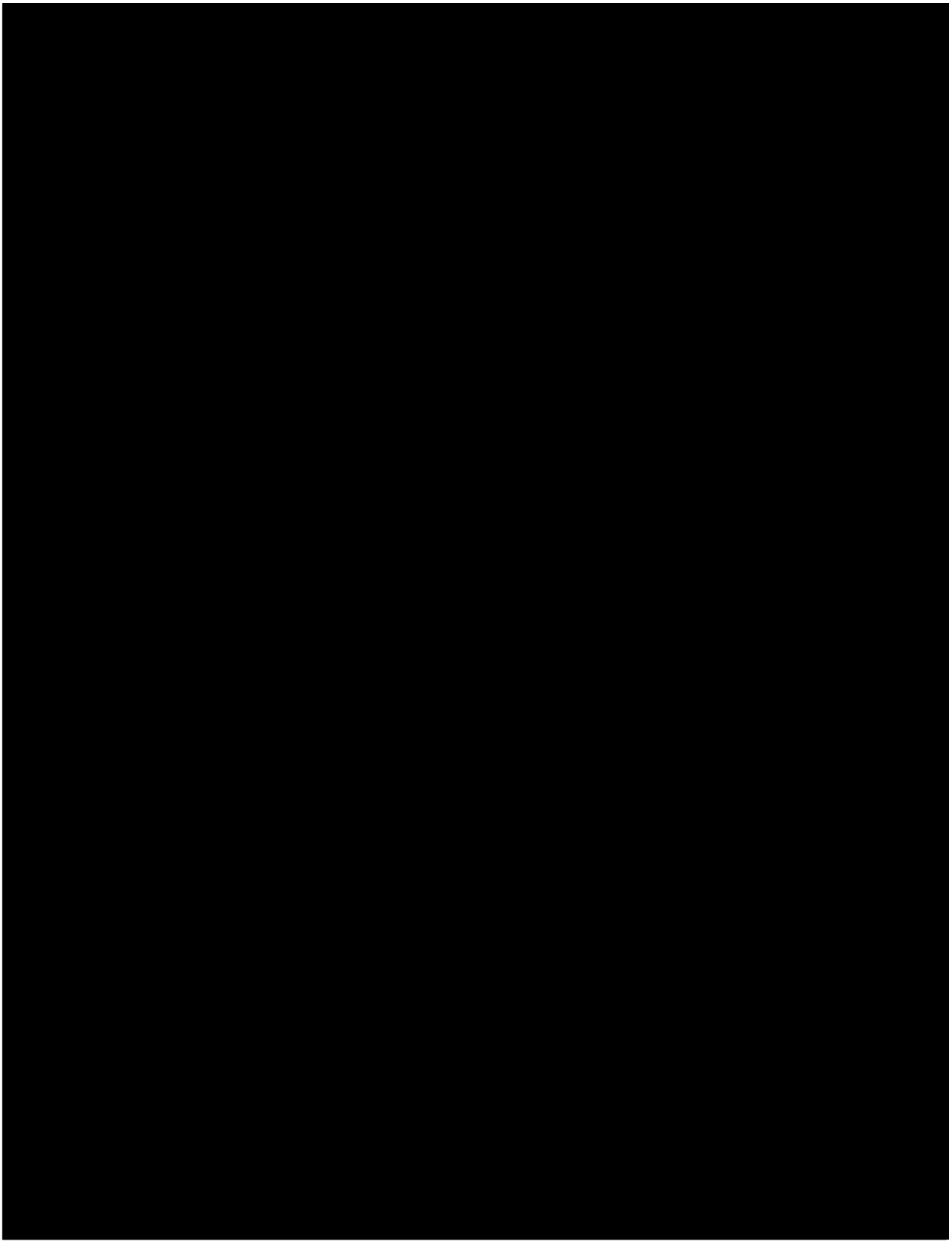

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