Roche Managed Master Research (Secondary Data Analysis) Agreement

Details of the parties	
Name of Institution:	**University of Canberra, represented by the Institute for Governance and Policy Analysis**
Address:	**University Drive South, Canberra ACT 2601, Australia**
ABN:	**81 633 873 422**
Contact for Notices:	**Professor Laurie Brown, Deputy Director IGPA**
Fax for Notices:	**+61 (0)2 6201 2751**
Phone Number:	**+61 (0)2 6201 2770**

Name of Sponsor:	**Roche Products Pty Limited**
Address:	**Level 8, 30-34 Hickson Road, Sydney**
	New South Wales 2000 Australia
ABN:	**70 000 132 865** ACN: **000 132 865**
Contact for Notices:	**Claire Parken, Senior Market Access Manager, Market Access and Public Policy**
Fax for Notices:	**61 2 9454 9284**
Phone Number:	**+61 2 9454 9343**

Date of Agreement:	**14 March 2018**

This agreement is made between the Sponsor and the Institution

Purpose of the Agreement

A. The Sponsor wishes to engage the Institution to conduct the Research Activities on the terms of this Agreement.

B. The Sponsor will be responsible for the initiation, management, and financing of the Research Activities.

C. The Institution will be is responsible for the conduct of the Research Activities which are under the control of the Institution.

Operative Provisions

1. INTERPRETATION

1.1 In this Agreement:

Affiliate means, with respect to any specified person or entity, any other person or entity that directly, or indirectly through one or more intermediaries, Controls or is Controlled by, or is under common Control with, the specified person or entity. With respect to the Sponsor, the term "Affiliate" shall not include Chugai Pharmaceutical Co. Ltd., 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324, Japan (**Chugai**) and Foundation Medicine, Inc., 150 Second Street, Cambridge, MA 02141, USA (**FMI**) and their respective subsidiaries, unless Roche opts for such inclusion of Chugai and/or FMI and their respective subsidiaries by giving written notice to the Institution.

Agreement means this Agreement, including all the Schedules.

Background Intellectual Property (**Background IP**) of a party means information, techniques, know-how, software and materials (regardless of the form or medium in which they are disclosed or stored) that are provided by or on behalf of that party to the other for use in the Research Activity (whether before or after the date of this Agreement) or used by that other party in conducting the Research Activity, and all Intellectual Property in them, but excludes the Research Materials.

Commencement Date means the date specified on the first page of this Agreement or, if such date is not included, on the date this Agreement is last signed by either the Sponsor or Institution

Confidential Information means:

(1) in respect of the Sponsor:

(a) all information collected in the course of, resulting from, or arising directly out of the conduct of a Research Activity;

(b) the Research Plan, information related to a Research Plan and Research Materials;

(c) know-how, methodology, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Sponsor or its Affiliates;

(d) information concerning the business affairs or clients of the Sponsor or its Affiliates;

(2) in respect of the Institution, information in relation to the Institution's business, transactions, operations, financial arrangements, strategies, intellectual or other property, actual or prospective suppliers or competitors, information that is either marked "confidential" or by its nature is intended to be confidential,

but Confidential Information does not include Personal Information.

Data means all data required to be delivered to the Sponsor in accordance with a Research Plan.

Essential Documents means documents which individually and collectively permit evaluation of the conduct of a Research Plan and the quality of the Data produced.

GST means the Goods and Services Tax payable under a GST Law.

GST Law means the same as in A New Tax System (Goods and Services Tax) Act 1999 (Cth) as amended from time to time, and any regulations made pursuant to that Act.

Institution means the body so described on the first page of this Agreement.

Intellectual Property means all present and future industrial and intellectual property rights, including without limitation:

(1) inventions, patents, copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders rights, registered designs, registered and unregistered trade marks, know how, trade secrets and the right to have confidential information kept confidential, and any and all other rights to intellectual property which may subsist anywhere in the world; and

(2) any application for or right to apply for registration of any of those rights.

NHMRC means the National Health and Medical Research Council of the Commonwealth of Australia.

Personal Information has the same meaning as in the Relevant Privacy Laws.

Personnel means employees, agents and/or authorised representatives, and includes, in the case of the Institution, the Principal Investigator.

Research Plan means the document identified in a Research Request Form which describes the objective(s), design, methodology, statistical considerations and organisation of a Research Activity and, subject to **clause 2.3**, as amended from time to time, as agreed by the parties, and, where applicable, most recently approved by the Reviewing HREC.

Publish means to publish, by way of a paper, article, manuscript, report, poster, internet posting, presentation slides, abstract, outline, video, instruction material or other disclosure, the Study Materials, in printed, electronic, oral or other form.

Publication has a corresponding meaning.

Regulatory Authority means any body which has jurisdiction over the conduct of the Research and includes the TGA and any overseas regulatory authorities who may audit, or require to be audited, any part of the Research Activity or Research Materials.

Relevant Privacy Laws means the *Privacy Act 1988* (Cth), the *Information Privacy Act 2014* (ACT) and any other legislation, code or guideline which applies in the jurisdiction in which the Study Site is located and which relates to the protection of Personal Information.

Research Activities means research with secondary data analysis requested by the Sponsor in a Research Activity Request Form generating evidence which is likely to be used by Sponsor to

inform external bodies and/or to be published in peer reviewed journals or at scientific congresses.

Research Completion means the delivery to the Sponsor by the Institution of all Data required by the Research Plan together with all Essential Documents and, where applicable, a copy of the letter from the Reviewing HREC acknowledging receipt of the final report and/or closure letter from the Institution.

Research Materials means all the materials and information created for the Research Activity, or required to be submitted to the Sponsor including all Data in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not, relating to the Research, which are discovered or developed as a result of the Research.

Research Request Form means any document agreed in accordance with **clause 2.1**using the template at Schedule 1 to this Agreement.

Reviewing HREC means any relevant Human Research Ethics Committee reviewing a Research Activity on behalf of the Institution as described in a Research Request.

Sponsor means the corporate entity so described on the first page of this Agreement.

Term means three (3) years from the Commencement Date.

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

1.2 Except where the context otherwise requires:

(1) clause headings are for convenient reference only and are not intended to affect the interpretation of this Agreement;

(2) where any word or phrase has a defined meaning, any other form of that word or phrase has a corresponding meaning;

(3) any reference to a person or body includes a partnership and a body corporate or body politic;

(4) words in the singular include the plural and vice versa;

(5) all the provisions in any schedule to this Agreement are incorporated in, and form part of, this Agreement and bind the parties;

(6) a reference to a replacement of a document or standard, means any document or ruling which amends, updates, replaces or supersedes that document or standard;

(7) if a period of time is specified and dates from a given day or the day of an act or event, it is to be calculated inclusive of that day;

(8) a reference to a monetary amount means that amount in Australian currency; and

(9) references to a party includes its Personnel.

2. THE RESEARCH ACTIVITY

2.1 Where the Sponsor wishes the Institution to undertake a Research Activity:

(1) Sponsor may issue a Research Request Form in the form of the template set out in Schedule 1 of this Agreement and upon execution by both parties it will become a Research Activity for the purposes of this Agreement.

(2) This Agreement acts as a master agreement between Sponsor and Institution in respect of each Research Activity.

(3) Any Research Request Form agreed pursuant to this Agreement is subject to all of the terms of this Agreement.

(4) Unless otherwise expressly agreed in writing by the parties, Institution is not obliged to perform any obligations and Sponsor is not obliged to pay the Institution in the absence of a Research Request Form complying with this Agreement being executed in respect of a Research Activity.

2.2 The parties must comply with, and conduct the Research Activity in accordance with, the Research Plan and, where applicable, any conditions of the Reviewing HREC. In addition the parties must comply with the following, as applicable:

(1) any requirements of relevant Commonwealth or State or Territory laws or of Regulatory Authorities;

(2) the NHMRC National Statement on Ethical Conduct in Human Research (2007) or its replacement,; and

(3) the Roche Quality Policy regarding Scientific Credibility Standards for Evidence Generation .

2.3 From time to time, the parties may agree to modify the Research Plan. Except where the modification involves only logistical or administrative aspects of the Research Activity, where the Institution's Reviewing HREC requires approval of the Research Activity, any modification may not be implemented before approval by the Reviewing HREC. Any modification to the Research Plan must be in writing and signed by the parties.

2.4 **Obligations and responsibilities of the Institution**

The Institution is responsible for ensuring that:

(1) where required, written approval has been obtained to conduct the Research Activity from the Reviewing HREC prior to Research initiation. Any such written documentation of approval by the Reviewing HREC must be provided to the Sponsor;

(2) the Research Activity is conducted according to the Research Plan without changes, except as provided in this Agreement.;

(3) where required, any amendments to the Research Plan are approved by the Reviewing HREC and Sponsor prior to implementation of the amendment;

(4) the Sponsor is provided with a list of appropriately qualified persons to whom they have delegated significant Research-related duties;

(5) where relevant, all patient identifying information is removed from all records being transferred to the Sponsor;

(6) it provides regular written progress reports to the Sponsor in relation to the Research Activity as required by the Research Plan;

(7) it completes and returns to the Sponsor as required any Research Activity related materials within a reasonable time period;

(8) it is not subject to any obligations, either contractually or in any other way, which would unreasonably interfere with or prohibit the performance of work related to any Research Activity;

(9) any Personnel who assist in the conduct of a Research Activity are informed of and agree to abide by all terms of this Agreement relevant to the activities they perform.

2.5 The Institution warrants that, to the best of its knowledge, it and its Affiliates and any other person involved in the conduct of a Research Activity, are properly registered with appropriate professional registration bodies, have not been disqualified from practice or disbarred by any Regulatory Authority. Furthermore, the Institution shall notify the Sponsor as soon as practical after it becomes aware of any such disqualification or disbarment.

2.6 The Institution will not engage in any conduct on the Sponsor's behalf which is in violation of, or potentially in violation of, any applicable local or foreign laws or regulations.

2.7 The Institution warrants, represents and undertakes to the Sponsor that it has not offered, promised or paid, either directly or indirectly, any Benefit to a government official (including, but not limited to, a healthcare professional employed by a government-owned healthcare facility) to induce such government official to act in any way in connection with his or her official duties with respect to services performed under this Agreement or to otherwise obtain an improper advantage for the Institution or the Sponsor (**Improper Payment**), and has not received an Improper Payment, and will not offer, promise, pay, authorise or receive any Improper Payment in the future. For the purposes of the foregoing, Benefit includes but is not limited to money, financial or other advantage, travel expenses, entertainment, business or investment opportunities, charitable donations or any other thing of value.

2.8 The Institution must have adequate security measures to ensure the safety and integrity of the Essential Documents and Research Activity records and reports and any Research Activity related materials.

2.9 The Institution will make available adequate facilities, equipment and any other resource of the Institution reasonably required to safely follow the Research Plan, provided that any amendments to the Research Plan which take place after the execution of this Agreement and requiring any additional use of facilities, equipment, staff or resources, have been approved in writing by the Institution and, where applicable, the Reviewing HREC.

2.10 The Institution will have an adequate number of appropriately qualified Personnel for the foreseen duration of the Research Activity and ensure that such Personnel are adequately informed about the Research Plan and their Research Activity related duties and functions.

2.11 The Institution must retain and preserve a copy of all Research Materials for at least 5 years from Research Activity Completion and must ensure that no Research Activity related materials are destroyed before the expiration of this time period without the written approval of Sponsor. The Institution agrees to notify the Sponsor in writing before destroying any Research Materials.

2.12 The Institution will ensure that, where applicable, the Research Activity is subject to the continuing oversight of the Reviewing HREC throughout its conduct.

2.13 The Institution shall obtain approval, in writing, from the Sponsor for any press statements or promotional statements regarding the Research Activity before the statements are released, unless the statement or disclosure is required by:

(1) law;

(2) any policy, guideline or direction of government or any government department or agency; or

(3) any Regulatory Authority.

3. SPONSOR OBLIGATIONS AND RESPONSIBILITIES

3.1 The Sponsor will implement and maintain quality assurance and quality control systems with written standard operating procedures to ensure that the Research Activity can be conducted and data generated, documented, recorded and reported in compliance with all of the documents referred to in **clause 2.2**.

3.2 The Sponsor will designate appropriately qualified Personnel to advise on Research-Activity related scientific questions or problems.

4. PAYMENTS

4.1 In consideration of the Institution conducting the Research Activity, the Sponsor will pay the Institution in the manner and on the basis of the prices and at the times set out in in Annexure B of a Research Request Form. The prices set out in Annexure B of a Research Request Form do not include GST. At the time of payment, the Sponsor must pay to the Institution any amount of GST that the Institution is required to pay in addition to the prices set out in Annexure B of a Study Request Form and in accordance with GST Law.

4.2 Payments will be made by the Sponsor upon receipt of a valid tax invoice from the Institution.

4.3 The Sponsor and the Institution each warrant that they are registered under GST Law. Tax invoices must identify supplies for which GST is payable.

4.4 Unless indicated otherwise in a Research Plan or Annexure B of a Research Request Form, the final payment will be made following Research Completion.

4.5 No part of any consideration paid hereunder is for the recommending or arranging for the referral of business or the ordering of items or services.

4.6 Neither this Agreement nor any consideration paid hereunder is contingent upon the Institution's use or purchase of any of the Sponsor's products.

5. CONFIDENTIALITY

5.1 Subject to **clause 5.2**, each party must not, and must ensure their Personnel do not, use or disclose any Confidential Information of the other party, other than where and only to the extent that such use or disclosure is necessary for the performance of a Research Activity, the exercise of its rights or the performance of its obligations under this Agreement.

5.2 The Institution may use or disclose Sponsor Confidential Information in any of the following circumstances:

(1) for the purposes of complying with the Institution's internal complaint procedures , quality assurance activities, disciplinary procedures;

(2) for the purposes of complying with the requirements of any Regulatory Authority;

(3) to enable the Reviewing HREC to monitor the Research Activity;

(4) where the Sponsor consents in writing to the disclosure;

(5) as part of a publication issued under the provisions of **clause 7**;

(6) where release of the Confidential Information is required by law, with notice as soon as reasonably practical to the Sponsor, and subject to the Institution upon request providing reasonable assistance to enable the Sponsor to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure;

(7) for the purposes of legal advice; and

(8) disclosure to the Institution's insurer.

5.3 Where Confidential Information is disclosed in accordance with this **clause 5** the Confidential Information must only be used in connection with the legitimate purposes of the Institution, and only disclosed to those who have a need to know it for such purposes and are obligated to keep the information confidential.

5.4 The Sponsor may disclose Institution Confidential Information on a need to know and confidential basis to its Affiliates and for the purpose of obtaining legal advice. The Sponsor may disclose Institution Confidential Information if required by law, with notice as soon as reasonably practical to the Institution, and subject to the Sponsor upon request providing reasonable assistance to enable the Institution to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure.

5.5 The parties are responsible for ensuring that their Personnel are aware of the obligations in respect of Confidential Information in this **clause 5**, and are bound in similar terms to keep such information confidential.

5.6 Information will not be Confidential Information and subject to the provisions of this **clause 5** where:

(1) the information has been independently received from a third party who is free to disclose it;

(2) the information is in or has entered the public domain other than as a result of a breach of this Agreement;

(3) the party already knew the information, the prior knowledge of which it can document by prior written records; or

(4) the party independently develops, discovers or arrives at the information without use, reference to, or reliance upon, the Confidential Information.

6. PRIVACY

6.1 Each party must ensure that any Personal Information it obtains or holds as a result of the conduct of a Research Activity is collected, stored, used and disclosed by it in accordance with the Relevant Privacy Laws.

6.2 Each party will promptly report to the other party any unauthorised access to, use or disclosure of Personal Information of which it becomes aware, and will work with the other party to take reasonable steps to remedy such unauthorised access, use or disclosure.

6.3 The Institution agrees that the Sponsor may collect and use Personal Information of Personnel of the Institution (such as their full name and contact details) (**Institution Personnel Data**) for the purposes of this Agreement, including to:

(1) to fulfill any of the Sponsor's obligations under the Agreement;

(2) to fulfill the Sponsor's legal and/or regulatory obligations; and

(3) to maintain accuracy and completeness of Institution Personnel Data held by the Sponsor in accordance with this Agreement.

6.4 The Sponsor acknowledges that the Institution is bound by the *Information Privacy Act 2014* (ACT) (**Act**) and that the Sponsor will be provided access to personal information within the meaning of the Act for the purposes of this Agreement (including but not limited to personal information contained in Institutional Personnel Data).

6.5 Notwithstanding any other provision of this Agreement, the Sponsor agrees to

(1) not do an act, or engage in a practice, that would breach a Territory Privacy Principle (as set out in the Act, with the exception of TPP1) if that act or practice was done by the Institution;

(2) ensure that any subcontractor or Affiliate in receipt of personal information originating from the Institution does not do such an act or engage in such a practice; and

(3) immediately notify the Institution if the Sponsor becomes aware of a breach, or suspected breach, of any of its obligations under this clause 6.5 or other obligations with respect to privacy under this Agreement or at law.

6.6 Subject to clause 6.5, the Institution agrees that the Sponsor may store, maintain and process Institution Personnel Data on computers or web-based database systems managed by the Sponsor in Australia only for each of the purposes set out in **clause 6.3**. Any transmission of Institution Personnel Data outside of Australia must only be undertaken on the express written approval of the Institution, which approval must not be unreasonably withheld.

6.7 The Institution agrees to take reasonable steps to obtain all necessary consents from its Personnel for the collection, use and disclosure of Institution Personnel Data for the purposes set out in **clauses 6.3 and 6.6**. The Institution and its Personnel may contact the Sponsor with enquiries regarding the Sponsor's collection or use of Institution Personnel Data or make a complaint or request access to Institution Personnel Data held by the Sponsor.

7. PUBLICATIONS

7.1 The Sponsor and the Institution will jointly prepare and Publish the methods, results of, and conclusions from, each Research Activity, subject to this clause and in accordance with copyright law.

7.2 The Institution agrees that no Publication of the Research Activity results may be made by Institution unless:

(1) the Sponsor notifies the Institution in writing that it will not Publish the Research Activity or results for any Research Activity, in which event the Institution will have the right to Publish the Research Activity results for that Research Activity and the further provisions of this clause shall apply to any such Publication; or

(2) the Institution has made a written request to the Sponsor to Publish the Research Activity or results for any Research Activity the Sponsor approves such a request in writing.

7.3 The Institution must ensure, that in relation to each Research Activity to which clause 7.2 applies, it gives a copy of any proposed Publication drafted by them and/or other Personnel involved in the conduct of the Research Activity to the Sponsor at least 40 days before forwarding it to any person that is not bound by the confidentiality obligations set out in **clause 5**.

7.4 The Sponsor may, within that 40-day period do any one or more of the following:

(1) provide comments on the proposed Publication to the Institution, in which case the Institution must consider such comments but will not be bound to follow them;

(2) request delay of Publication for no more than 120 days to allow the Sponsor to file patent applications or take other measures to preserve or secure its Intellectual Property, in which case the Institution must abide by that request; or

(3) request that the Institution remove specified Confidential Information (other than the results of the Research Activity) from the Publication, in which case the Institution must remove such specified Confidential Information as is reasonably required to protect the Intellectual Property of the Sponsor.

7.5 If the Institution has not received any comments from the Sponsor on the proposed Publication within 40 days of giving a copy to the Sponsor under **clause 7.3**, the Institution may proceed to make the Publication.

7.6 Where the Sponsor intends to Publish the method, results or conclusions from a Research Activity, any person named as an author on that Publication will be required to fulfil the authorship criteria as set out by the International Committee of Medical Journal Editors.

7.7 In all Publications the Sponsor's support of the Research Activity shall be acknowledged.

7.8 The Sponsor may freely use, copy and disseminate any manuscript following its Publication in a journal without further obligation to the Institution.

7.9 The Sponsor may only use the Institution's name:

(1) in Research Activity publications and communications made to the Institution and any other person which is subject to substantially the same confidentiality obligations as those set out in **clause 5**, in relation to performance of the Research Activity; or

(2) in Research Activity publications and communications made to any third party not subject to the confidentiality obligations set out in **clause 5**, with the Institution's prior written consent.

8. SECONDARY DATA ANALYSIS RESEARCH SAFETY REPORTING OBLIGATIONS

8.1 **For a research with no studied medicinal product and no adverse events/safety information extracted as per research plan, the following safety reporting obligations apply:**
There is no studied medicinal product in this secondary data analysis research no adverse events/safety information will be extracted/analysed as per research plan, therefore the research report and final publication will not include a summary of adverse events or special situations.

8.2 **For a research with studied medicinal product and/or adverse events/safety information extracted as per research plan, the following safety reporting obligations apply:**
It is assumed that safety reporting of data which are going to be extracted/analysed as part of this Research Activity have been appropriately performed and documented at the time this data were collected through primary data collection mechanism.

This is a secondary data analysis research and the reporting of adverse events in the form of Individual Case Safety Reports (ICSRs) is not required. All adverse events and special situations extracted as per research plan will be summarised in any interim safety analyses and in the research report and final publication.

As per research plan, these aggregate summaries may include adverse events or special situations as defined below.

ADVERSE EVENTS
Adverse Event (AE) means any untoward medical occurrence in a patient, consumer or clinical investigation subject administered a medicine, which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicine, whether or not considered related to the medicine.

SPECIAL SITUATIONS

Special Situation Report means any of the following; pregnancy, breastfeeding, lack of efficacy, overdose, misuse, abuse, off-label use (intentional use of a medicinal product not in accordance with the authorized product information), medication error (including intercepted medication error and potential medication error), occupational exposure, drug interaction, data related to suspected transmission of an infectious agent via a medicinal product (STIAMP), suspected adverse reaction related to quality defect or falsified medicinal products (whether suspected or confirmed), reports from class action lawsuits, death cases.

In addition, reasonable attempts should be made to obtain and submit the age or age group of the patient when a case is reported by a healthcare professional, or consumer in order to be able to identify potential safety signals specific to a particular population.

9. RESEARCH MATERIALS AND INTELLECTUAL PROPERTY

9.1 The Sponsor grants to the Institution and its Personnel the right to use the Background IP of the Sponsor and the Research Materials as required to carry out the Research Activity and perform this Agreement. Except for this right, neither the Institution nor any of its Personnel acquires any right or interest in any Intellectual Property provided by or on behalf of the Sponsor.

9.2 In order to carry out the Research Activity, the Institution may use Intellectual Property which is part of the Institution's Background IP. Any such Background IP remains the sole property of the Institution. The Institution grants to the Sponsor and its Affiliates a non-exclusive, perpetual, royalty free, worldwide licence to use (including the right to sub-licence) the Institution's Background IP solely for the purpose of the commercialisation of the Research Materials.

9.3 Subject to **clause 8.2**, all Intellectual Property in the results of each Research Activity will vest automatically upon its creation in the Sponsor, and the Institution presently assigns to the Sponsor all Intellectual Property rights contained in those results . The Institution agrees to execute or procure the execution by its Personnel of any documents reasonably necessary to give effect to this assignment, at the Sponsor's expense.

9.4 The Institution must promptly disclose and communicate in writing to the Sponsor full particulars of any Intellectual Property that the Institution makes, discovers or conceives in the course of each Research Activity.

10. TERM AND TERMINATION

10.1 This Agreement commences on the Commencement Date and continues for the Term save that thereafter it will continue to the extent that, and for the purposes of completing, any Research Activity under this Agreement that was agreed and is in progress at the end of the Term and is not yet completed

10.2 A party may terminate this Agreement with 30 days prior written notice or such shorter time period as is reasonably required in the circumstances if the other party:

(1) is in breach of any obligations under the Agreement or the Research Plan (including without just cause to meet a timeframe) and fails to remedy such breach where it is capable of remedy within 30 days of a written notice from the terminating party specifying the breach and requiring its remedy;

(2) is declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business; or

(3) assigns this Agreement to a person considered unsuitable to perform the Agreement as set out in **clause 15.3.**

10.3 The Sponsor may terminate this Agreement if the Institution breaches **clause 2. 6** or if the Sponsor learns that the Institution is making, or has made, Improper Payments (within the meaning of **clause 2.7**) to government officials with respect to services performed on behalf of the Sponsor or any other company. Further, in the event of such termination, the Institution will not be entitled to any further payment or compensation.

10.4 The Sponsor may terminate this Agreement and/or any Research Activities with 30 days prior written notice to the Institution. In the event of such early termination, the Sponsor will pay the reasonable costs of the Institution relating to each terminated Research Activity calculated in accordance with the prices in the Payment Schedule set out in Annexure B of each such Research Request Form.

10.5 In the event of termination, the Institution must promptly initiate all appropriate action to close each or each relevant Research Activity and, subject to any applicable retention requirements imposed by law, return to the Sponsor (or destroy if requested by the Sponsor and where reasonably practicable for the Institution, and provide evidence of any such destruction) any materials received from the Sponsor in respect of each terminated Research Activity.

11. DISPUTES

11.1 No party may commence legal proceedings against another in respect of a dispute arising in relation to this Agreement (except for urgent interlocutory relief) unless the parties have complied with this clause and that party has first notified the other party in writing of the dispute and has used all reasonable endeavours to resolve the dispute with the other party within 28 days of the giving of that notice (**Initial Period**).

11.2 If the dispute is not resolved within the Initial Period, or within such longer period of time as these persons may agree in writing, the parties shall be free to pursue their rights at law in respect of the dispute.

11.3 Despite the existence of a dispute or difference between the parties, the parties must continue to comply with their obligations under this Agreement.

11.4 Nothing in this Agreement prevents a party from applying to a court for any urgent interlocutory or injunctive relief.

12. APPLICABLE LAW

This Agreement will be governed by, and construed in accordance with, the laws of New South Wales and the parties submit to the non- exclusive jurisdiction of the courts of New South Wales and courts entitled to hear appeals from those courts.

13. NOTICES

13.1 A notice, consent, approval or other communication (each a **notice**) under this Agreement must be:

(1) delivered to the party's address; or

(2) sent by pre-paid mail to the party's address; or

(3) transmitted by facsimile to the party's address.

13.2 A notice given by a party in accordance with this clause is treated as having been given and received:

(1) if delivered to a person's address, on the day of delivery if a business day, otherwise on the next business day; or

(2) if sent by pre-paid mail, on the third business day after posting; or

(3) if transmitted by facsimile to a person's address and a correct and complete transmission report is received, on the day of transmission if a business day, otherwise on the next business day.

13.3 The addresses of the parties for the purposes of giving any notice are set out on the front page of this Agreement.

14. WAIVER

14.1 No right under this Agreement is waived or deemed to be waived except by notice in writing signed by the party waiving the right. A waiver by any party in respect of any breach of a condition or provision of this Agreement will not be deemed to be a waiver in respect of any other breach.

14.2 Failure or delay by any party to enforce any provision of this Agreement will not be deemed to be a waiver by that party of any right in respect of any other such breach.

15. VARIATIONS

No variations of this Agreement are legally binding on any party unless evidenced in writing signed by all parties.

16. ASSIGNMENT

Neither party may assign its rights or novate its rights and obligations under this Agreement.

17. SUBCONTRACTING

Neither party may subcontract any of its obligations under this Agreement.

18. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the parties in relation to each Research Activity and supersedes all prior representations, agreements, statements and understandings, whether verbal or in writing in relation to each Research Activity.

19. FURTHER DOCUMENTS

Each party will do anything (including executing any document), and will ensure that its Personnel do anything (including executing any document), that the other party may reasonably require to give full effect to this Agreement.

20. SEVERANCE

If any part of this Agreement is prohibited, void, voidable, illegal or unenforceable, then that part is severed from this Agreement but without affecting the continued operation of this Agreement.

21. RELATIONSHIP OF THE PARTIES

Nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the parties and no party will hold itself out as an agent for another.

22. FORCE MAJEURE

If any party is delayed or prevented from the performance of any act required under this Agreement by reason of any act of God, act of nature, including any epidemic or outbreak of pandemic disease, fire, act of government or state, war, civil commotion, insurrection, embargo, prevention from or hindrance in obtaining raw material, energy or other supplies, labour disputes of whatever nature or whatever reason beyond the control of the party (a **Force Majeure Event**), the affected party shall promptly notify the other party in writing, giving details of the Force Majeure Event, the acts affected by the Force Majeure Event and the extent to which they are affected, and performance of such acts shall be excused for the period of such event provided that if such interference lasts for any period in excess of 30 days either party may, by written notice to the other, terminate this Agreement.

23. COUNTERPARTS

This Agreement may be executed in any number of counterparts. All counterparts taken together are deemed to constitute one and the same Agreement.

24. SURVIVAL

Any clause of this Agreement which, by its nature, must survive any termination of this Agreement will be deemed to survive such termination. Without limitation, **clauses 5,6,7,8, 12** and this **clause 23** will survive any termination or expiry of this Agreement.

25. CONFLICT

In the event of any inconsistency between this Agreement and a Research Request Form or the Research Plan, this Agreement prevails.

In witness hereof, the parties have caused this Agreement to be executed as of respective dates written below.

Signed on behalf of the **Sponsor**

Signed: [signature]

Name: CARLENE TODD

Position: DIRECTOR, MARKET ACCESS & PUBLIC POLICY

Date: 28 / 3 / 18

Signed on behalf of the **Sponsor**

Signed: [signature]

Name: BRENDA POPE

Position: GROUP MARKET ACCESS MANAGER

Date: 27 / 3 / 18.

Signed on behalf of the **Institution**

Signed: [signature]

Name: GEORGE CHO

Position: Ag DVCR & I

Date: 21 / 3 / 18

Witness: [signature]

Name: KARINA MARIA DOBLANDER-AZURIN

SCHEDULE 1
Template Research Request Form

This Research Request Form is made on the date set out in Item 1 of clause 5.

Parties

Roche Products Pty Limited ABN 70 000 132 865 of Level 8, 30 – 34 Hickson Rd, Sydney NSW 2000 (**Roche**)
and
University of Canberra ABN 81 633 873 422 of University Drive, Bruce, ACT 2617 (**Institution**)

Background

Roche and Institution entered into a **Roche Managed Master Research (Secondary Data Analysis) Agreement** on the date set out in Item 2 of clause 5 (**Agreement**).

Operative Provisions

(a) This Research Request Form is made pursuant to clause 2.1 of the Agreement.

(b) This Research Request Form (and any attachments) incorporates the terms and conditions of the Agreement, as amended from time to time.

(c) In the event of there being any conflict or inconsistency between any of the parts of this Agreement (unless expressly stated otherwise), clause 24 of the Agreement will apply.

Institution will conduct the Research Activity as described in Item 3 of clause 5 in accordance with the Research Plan at Annexure A of this Research Request Form and the terms of the Agreement.

The agreed payments in respect of the conduct of the Research Activity will be as described in the Payment Schedule at Annexure B to this Research Request Form.

Payment will be made in accordance with clause 4 of the Agreement.

In the event of early termination of the Research Activity, payment will be made pro-rata in respect of all fees described in the Payment Schedule at Annexure B to this Research Request Form which have accrued and are non-cancellable up to and including the date of termination.

All payments will be made payable by Electronic Funds Transfer (EFT) to the account nominated in Item 4 of clause 5.

The Sponsor reserves the right to refuse to pay invoices received from the Institution more than four (4) calendar months following completion of the Research Activity, unless otherwise previously agreed between the parties in writing.

The contact person for each party in respect of the Services is set out in Item 5 of clause 5.

1.	**Date of Research Request Form**	

2.	**Date of Agreement**	
3.	**Research Activity**	Research Activity name: Reviewing HREC (if any):
4.	**Institution Payment Details**	Account Name: Account Number: Bank Name: Bank Address: Bank Number:
5.	**Contacts**	

Executed for and on behalf of **Roche Products Pty Limited ABN 70 000 132 865** by or in the presence of:

Signature

Name and Position

Date

Signature

Name and Position

Date

Executed for and on behalf of **University of Canberra ABN 81 633 873 422** by or in the presence of:

Signature	Signature
Name and Position	Name and Position
Date	Date

ANNEXURE A
Research Plan

ANNEXURE B
Payment Schedule

The amount of payment due to the Institution for the Research Activity will be at the rates/in the amounts provided in the Payment Schedule below:

PAYMENT SCHEDULE

MILESTONE	Payment (AUD excluding GST)