Government of **Western Australia**
Department of **Health**
North Metropolitan Health Service
Women and Newborn Health Service

Research Governance Office
17th September 2014

Professor Jan Dickinson
School of Women's and Infants Health
King Edward Memorial Hospital
374 Bagot Rd
Subiaco, WA 6008

Dear Professor Dickinson,

Project Title: **STRIDER (NZAus): Randomised Controlled Trial of Sildenafil Therapy in Dismal Prognosis Early-Onset Intrauterine Growth Restriction (New Zealand and Australia) - WA submission**

HREC Reference: **2014071EW**

On behalf of the Women and Newborn Health Service, I give authorisation for your research project to be conducted at the following site(s):

KEMH

This authorisation is based on the approval from the WNHS HREC and the review from the Research Governance Office. This authorisation is valid subject to the ongoing approval from the HREC.

This authorisation is based on the ethical approval from the HREC, and on the basis of compliance with the 'Conditions of Authorisation to Conduct a Research Project at Site' (attached) and with the compliance of all reports as required by the Research Governance Office and approving HREC. Non compliance with these requirements could result in the authorisation being withdrawn.

The responsibility for the conduct of this project remains with you as the Principal Investigator at the site.

Yours sincerely

Dr Mark Salmon
Executive Director
Medical Services

Government of **Western Australia**
Department of **Health**
North Metropolitan Area Health Service
Women and Newborn Health Service

CONDITIONS OF SITE AUTHORISATION TO CONDUCT A RESEARCH PROJECT

The following general conditions apply to the research project authorised to be conducted at the site(s) nominated in the accompanying letter. The acceptance of the site authorisation will be deemed to be an acceptance of these conditions by all investigators involved in the research project at the nominated site(s).

1. The responsibility for the conduct of project at a site lies with the nominated Principal Investigator (PI) at that site, all correspondence should be signed by PI.
2. The PI will inform the Research Governance Office (RGO) about any changes to the project. The PI is responsible for submitting any amendments to the approved documents listed on the approval letter, or any new documentation to be used in the project. Any new or amended documentation should be submitted in a timely manner and cannot be implemented at this site until they have received HREC approval for use at site(s).
3. The PI will notify the RGO of their inability to continue as PI at the site(s) and will provide the name and contact information of their replacement.
4. The PI will notify the RGO of any departures of named site investigators. The PI will also notify the RGO if any new site investigators join the project.
5. The PI is responsible for reporting site adverse events, using the standard forms available from the website. Reporting requirements are as per the WA Health Research Governance and Single Ethical Review Standard Operating Procedures. Additional reports, other than those outlined, that are submitted will be returned without acknowledgement.
6. The annual report that is submitted to the HREC should also be submitted to the RGO. This should include the site specific information which should be completed by the site PI.
7. The site has the authority to audit the conduct of any project without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred, if a complaint is received from a third party or the site decides to undertake an audit for Quality Improvement purposes.
8. The site can conduct random monitoring of any project. The PI will be notified if their project has been selected. The PI will be given a copy of the monitor's report along with the HREC and RGO.
9. Complaints relating to the conduct of a project should be directed to the RGO and will be promptly investigated according to the site Standard Operating Procedures.
10. The PI is reminded that records of consent or authorisation for participation in a project form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000.* A copy of the 'Participant Information Sheet' should also be included in the medical records as part of informed consent documentation.
11. Once the project has been closed at site, the PI is required to submit to the RGO a copy of the final report that is submitted to the HREC. This should include the site specific information which should be completed by the site PI. If the report is not received within 30 days the project will be closed and archived. An outstanding final report could impact on the PI's ability to apply for approval for future projects.

Government of **Western Australia**
Department of **Health**

WOMEN AND NEWBORN HEALTH SERVICE

11 August 2014

Dr Jan Dickinson
Professor Maternal Fetal Medicine
School of Women's and Infant's Health
King Edward Memorial Hospital for Women
374 Bagot Road
SUBIACO WA 6008

Dear Dr Dickinson

Project Title: **STRIDER (NZAus): Randomised Controlled Trial of Sildenafil Therapy in Dismal Prognosis Early-Onset Intrauterine Growth Restriction (New Zealand and Australia) - WA submission**

HREC Reference: **2014071EW**

The ethics application for the project referenced above was reviewed by Women and Newborn Health Service Human Research Ethics Committee (HREC) at its meeting on Tuesday 05 August 2014. It has been approved and the following documents have been approved for use in this project.

Document
NEAF version 2013-V2.1
NZAus Postnatal Questionnaire Version 1:18Mar2014
Patient Information Sheet and Consent Form

Approval of this project from Women and Newborn Health Service Human Research Ethics Committee (HREC, EC00350) is valid to **05 August 2017** and on the basis of compliance with the 'Conditions of HREC Approval for a Research Project' (attached).

The nominated participating site(s) in this project is/are:

King Edward Memorial Hospital for Women

[Note: If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

Government of **Western Australia**
Department of **Health**

WOMEN AND NEWBORN HEALTH SERVICE

This letter constitutes ethical approval only. This project cannot proceed at any site until separate site authorisation has been obtained from the CE, or delegate, of the site under whose auspices the research will be conducted at that site.

The Newborn Health Service Human Research Ethics Committee is registered with the Australian Health Ethics Committee and operates according to the NHMRC National Statement on Ethical Conduct in Human Research and International Conference on Harmonisation – Good Clinical Practice.

Should you have any queries about the HREC's consideration of your project, please contact Mrs Karen Taylor-Ellis on 9340 7845 or by email on karen.p.taylor@health.wa.gov.au. The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.kemh.health.wa.gov.au/development/resources/ethics.htm

Yours sincerely

Dr Mark Salmon
Executive Director
Medical Services

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Government of Western Australia
Department of Health
North Metropolitan Area Health Service
Women and Newborn Health Service

CONDITIONS OF HREC APPROVAL FOR A RESEARCH PROJECT

The following general conditions apply to the research project approved by the Human Research Ethics Committee (HREC) and acceptance of the approval will be deemed to be an acceptance of these conditions by all investigators involved in the research project:

1. The responsibility for the conduct of projects lies with the Coordinating Principal Investigator (CPI), all correspondence should be signed by CPI.
2. Projects that do not commence within 12 months of the approval date may have their approval withdrawn and the project closed. The CPI must outline why the project approval should stand.
3. The submission of an application for HREC approval will be deemed to indicate that the investigator/s and any sponsor recognises the approving HREC is registered with the National Health and Medical Research Council (NHMRC) and that it complies in all respects with the National Statement on Ethical Conduct in Human Research and all other national and international ethical requirements. **The HREC will not enter into further correspondence on this point.**
4. A list of attendance at a specific meeting is available on request, but no voting records will be provided.
5. The CPI will notify the HREC of his or her inability to continue as CPI and will provide the name and contact information of their replacement. Failure to notify the HREC can result in the project being suspended or approval withdrawn.
6. The CPI will notify the HREC of any departures of named investigators. The CPI will also notify the HREC if any new investigators and/or sites join the project that will utilise the HREC's approval.
7. The CPI will inform the HREC about any changes to the project. The CPI is responsible for submitting any amendments to the approved documents listed on the approval letter, or any new documentation to be used in the project. Any new or amended documentation should be submitted in a timely manner and cannot be implemented at any participating site until they have received HREC approval.
8. The CPI is responsible for reporting adverse events, indicating whether or not the project should continue. Reporting requirements are as per the WA Health Research Governance and Single Ethical Review Standard Operating Procedures. Additional reports other than those outlined that are submitted to the HREC will be returned without acknowledgement. The HREC can request additional reporting requirements as a special condition of a research project.
9. Where a project requires a Data Safety Monitoring Board (DSMB) it is the CPI's responsibility to ensure this is in place before the commencement of the project and the HREC notified of this. All relevant reports from the DSMB should be submitted to HREC.
10. For projects where the site is acting as the sponsor (ie. investigator initiated project) it is the responsibility of the CPI to report serious and unexpected drug/device reactions, as well as other reactions/events to the Therapeutic Goods Administration (TGA). Please refer to TGA website for further information and the relevant forms (see http://www.tga.gov.au/pdf/clinical-trials-guidelines.pdf p71 for medications or p77 for devices).

Department of Health
Government of Western Australia

Clinical Trial Research Agreement

For an Investigator-Initiated Study

Any textual change to the body of this Agreement is to be ignored, and reference instead had to the standard form, as amended by Schedule 4 by way of Special Conditions.

Details of the parties

Institution: The Minister for Health who is incorporated as the board of **Women and Newborn Health Service**, under s7 of the *Hospitals and Health Services Act 1927* (WA) and who has delegated all of the powers and duties as such to the Director General of Health

Name: Professor Jan Dickinson

Address 374 Bagot Road, Subiaco, Perth, Western Australia, Australia

ABN: 13 993 250 709

Contact for Notices: Professor Jan Dickinson

Fax for Notices: (08) 9381 3031

Phone Number: (08) 9340 1331

Organisation: The University of Auckland

Address: Department of Obstetrics & Gynaecology, FMHS, Park Road, Grafton, Auckland, New Zealand

ABN: N/A

Contact for Notices: Manager Agreements, ro-agreements@auckland.ac.nz

Fax for Notices: Dr Katie Groom, Lead Principal Investigator, +64 9 303 5969

Phone Number: +64 9 373 7599 ext 89656

Study Name: STRIDER NZAus

Protocol Number: Version 4, December 2013

Date of Agreement:

This agreement is made between the Institution and the Organisation

Purpose of the Agreement

According to this Agreement:

A. The Organisation has prepared and owns the Protocol. The Organisation may also agree to support the Study in other ways - for example, by providing funding for the Study or facilitating the supply of Investigational Product.

B. The Institution, through the Principal Investigator, is responsible for the initiation and conduct of the Study at the Study Site(s) which is/are under the control of the Institution.

C. The Study will be conducted on the terms and conditions set out below.

Operative Provisions

1. INTERPRETATION

1.1 In this Agreement:

Adverse Event has the meaning given in the TGA document "Access to Unapproved Therapeutic Goods – Clinical Trials in Australia" (October 2004) or replacement.

Agreement means this Agreement, including all the Schedules hereto.

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

Background Intellectual Property 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 one party to the other for use in the Study (whether before or after the date of this Agreement), except any Study Materials.

Biological Samples means any physical samples obtained from Study Subjects in accordance with the Protocol.

Case Report Form means a printed, optical or electronic document or database designed to record all of the information, required by the Protocol, to be reported to the Organisation on each Study Subject.

Confidential Information means:

(1) in respect of the Organisation:

(a) all information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Study Site or elsewhere;

(b) the Protocol, the Investigator's Brochure, information relating to the Protocol, Study Materials and Investigational Product;

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

(d) know-how, methodology, trade secrets, processes, sequences, structure and organisation of the Study; and

(e) information concerning the business affairs or clients of the Organisation or its Affiliates;

(2) in respect of the Institution, information in relation to the Institution's business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors;

but Confidential Information does not include Personal Information.

Equipment means the equipment supplied to the Institution for the purposes of the Study.

Essential Documents means documents which individually and collectively permit evaluation of the conduct of the Study and the quality of the data produced.

GCP Guideline means the Committee for Proprietary Medicinal Products (CPMP)/International Conference on Harmonisation (ICH) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) as adopted with annotation by the TGA, as amended from time to time.

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 industrial and intellectual property rights, including without limitation:

(1) patents, copyright, future 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, any and all other rights to intellectual property which may subsist anywhere in the world; and

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

Investigational Product is the medicine or device being trialled or tested in the Study and includes where relevant any placebo.

Investigator's Brochure is a compilation of the clinical and non-clinical data on the Investigational Product(s) which are relevant to the study of the Investigational Product in humans.

Multi-centre Study is a Study conducted by several investigators according to a single protocol at more than one study site.

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

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

Personal Information has the same meaning as in the *Privacy Act 1988* (Cth)

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

Principal Investigator is the person responsible for the conduct of the Study at the Study Site as described in **Schedule 1**.

Protocol means the document identified in **Schedule 3** which describes the objective(s), design, methodology, statistical considerations and organisation of the Study, as such document may be amended from time to time and most recently approved by the Responsible HREC.

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 of Study Materials, in printed, electronic, oral or other form. **Publication** has a corresponding meaning.

Regulatory Authority means any government body which has jurisdiction over the conduct of the Study at the Study Site and includes the TGA and any overseas regulatory authorities that may require to audit any part of the Study or Study Materials.

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

Responsible HREC means the Human Research Ethics Committee reviewing the Study on behalf of the Institution as described in **Schedule 1**.

Serious Adverse Event has the meaning given in the TGA document "Access to Unapproved Therapeutic Goods – Clinical Trials in Australia" (October 2004) or replacement.

Study means the investigation to be conducted in accordance with the Protocol.

Study Completion means the database has been locked and all Essential Documents have been provided to the Organisation, including a copy of the letter from the Responsible HREC acknowledging receipt of the final report and/or closure letter from the Principal Investigator.

Study Materials means all the materials and information created for the Study including all data, results, Biological Samples, Case Report Forms, (or their equivalent) in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Study which are discovered or developed as a result of the Study.

Study Site means the location(s) under the control of the Institution where the Study is actually conducted.

Study Subject means a person recruited to participate in the Study.

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) 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;

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

(8) references to the Organisation include its Personnel.

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

2. STUDY

2.1 Conduct of the Study

The parties must comply with, and conduct the Study in accordance with the Protocol and any condition of the Responsible 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 requirements of the TGA in Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004) or replacement and any other TGA publication or guideline that relates or may relate to clinical trials, or other such regulations or guidance governing the conduct of clinical research in the jurisdiction of the Study;

(3) the GCP Guideline;

(4) the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 1996; and

(5) the NHMRC National Statement on Ethical Conduct in Human Research (2007) or replacement, and any other relevant NHMRC publication or guideline that relates or may relate to clinical trials.

2.2 Protocol

The parties agree that the Organisation owns, and is responsible for, the Protocol.

2.3 If any issue relating to the safety of Study Subjects arises which requires a deviation from the Protocol, the Institution through the Principal Investigator may immediately make such a deviation without breaking any obligations under this Agreement. If there is a need for such a deviation the Institution must notify the Organisation and the responsible HREC of the facts and circumstances causing the deviation as soon as is reasonably practical, but in any event no later than 5 working days after the change is implemented.

3. PRINCIPAL INVESTIGATOR

3.1 Role of Principal Investigator

The Institution has authorised the Principal Investigator as the person responsible on a day-to-day basis for the conduct of the Study. The Principal Investigator does not have authority on behalf of the Institution to amend this Agreement or the Protocol.

3.2 Liability for Principal Investigator

For the purpose of this Agreement only, and as between the Organisation and the Institution only, the Institution agrees to be responsible for the acts and omissions of the Principal Investigator in relation to the conduct of the Study, to the extent that such responsibility would attach to the Institution in accordance with its obligations

under this Agreement or under the common law on the basis that the Principal Investigator is acting as an employee of the Institution. Nothing in this clause or Agreement affects any pre-existing contractual or other arrangement which may be in place between the Institution and the Principal Investigator.

3.3 Obligations and responsibilities

The Institution is responsible for ensuring that the Principal Investigator:

(1) thoroughly familiarises himself or herself with the appropriate use of the Investigational Product(s), as described in the Protocol, Investigator's Brochure, information relating to the Investigational Product and any other information sources provided by the Organisation;

(2) ensures written approval has been obtained to conduct the Study from the Responsible HREC and the Institution prior to Study initiation.

(3) conducts the Study according to the Protocol without changes except as provided in **clause 2.3**, or as agreed to in writing by the Organisation and the Institution and approved in accordance with **clause 3.3(4);**

(4) ensures that any amendments to the Protocol are approved by the Responsible HREC and the Organisation prior to implementation of the amendment;

(5) notifies the Organisation, the Institution and the Responsible HREC of any Adverse Events (including Serious Adverse Events) that occur during the course of the Study in accordance with the Protocol, and relevant ethical and regulatory guidelines, and in the case of the Institution and the Responsible HREC with their policies and procedures;

(6) ensures that informed consent to participate in the Study is obtained from each Study Subject prior to their enrolment in the Study and documented using an information and consent document which has been reviewed and approved by the Organisation, the Institution and the Responsible HREC.

4. INSTITUTION

4.1 Obligations and responsibilities

(1) If the Principal Investigator leaves the Institution or otherwise ceases to be available, the Institution must consult with the Organisation and use reasonable endeavours to nominate as soon as practicable a replacement reasonably acceptable to both Parties. If the parties cannot agree on a replacement, either party may terminate this Agreement in accordance with clause 13.5.

(2) The Institution will not engage in any conduct on the Organisation's behalf which is in violation of, or potentially in violation of, any applicable local laws or regulations.

(3) The Institution will make available adequate facilities, equipment and any other resource of the Institution reasonably required to safely follow the Protocol, provided that any amendments to the Protocol 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 Responsible HREC.

(4) The Institution will have an adequate number of appropriately qualified Personnel for the foreseen duration of the Study and ensure that such Personnel are adequately informed about the Protocol, Investigational Product(s), and their Study related duties and functions. The Personnel

appointed by the Institution to assess Study Subjects will attend an investigator meeting or a pre-study/initiation meeting, where appropriate.

(5) The Institution must retain and preserve a copy of all Study Materials, including copies of signed consent forms, Case Report Forms, Protocol, information relating to the Investigational Product, correspondence and investigator files for at least 15 years from Study Completion and must ensure that no Study related materials are destroyed before the expiration of this time period without the written approval of Organisation. The Institution agrees to notify the Organisation before destroying any Study Materials and agrees to retain the Study Materials for such longer period as reasonably required by the Organisation at the Organisation's expense.

(6) The Institution will ensure that the Study is subject to the continuing oversight of the Responsible HREC throughout its conduct.

5. ORGANISATION

5.1 Obligations and responsibilities

(1) Prior to the Agreement being executed, the Organisation will provide the Principal Investigator, and through the Principal Investigator the Institution and the Responsible HREC, with all current and relevant information that is required to justify the nature, scope and duration of the Study and to the extent that it is relevant to the Protocol.

(2) The Organisation will notify the Institution of any Adverse Events (including Serious Adverse Events) of which it becomes aware that occur during the course of the Study which may require alteration of the conduct of the Study, or which may affect the rights, interests, safety or well-being of Study Subjects.

(3) The Organisation will cooperate with the Institution and/or the Responsible HREC in investigating any Adverse Event (including Serious Adverse Event) arising out of or in connection with the Study.

6. FUNDING

6.1 In consideration of the Institution conducting the Study, the Organisation will provide to the Institution the funding amounts set out in **Schedule 2** in the manner set out in **Schedule 2.** The amounts set out in **Schedule 2** do not include GST. At the time of providing the relevant amounts, the Organisation must provide to the Institution any amount of GST that the Institution is required to pay in addition to the amounts set out in **Schedule 2**, and in accordance with GST Law.

6.2 Payment of the relevant amounts will be made by the Organisation upon either receipt of a valid tax invoice or a "Recipient Created Tax Invoice" issued by the Organisation.

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

6.4 In the event of early discontinuation of the Study or termination of this Agreement, if requested by the Organisation, the Institution must reimburse any amount of funding provided by the Organisation that has not been expended by the Institution up until the date of discontinuation of termination.

7. INVESTIGATIONAL PRODUCT

7.1 If the Organisation facilitates the supply to the Institution of any Investigational Product for use in the Study, the Organisation must ensure that all supplied Investigational Product is packaged in safe and appropriately labelled containers.

7.2 In relation to any Investigational Product supplied by the Organisation, the Institution must:

(1) ensure that it is used strictly according to the Protocol and not used for any other purposes, unless agreed in writing by the Organisation;

(2) provide a written explanation accounting for any missing Investigational Product;

(3) not charge any Study Subject or third party payer for it;

(4) keep it under appropriate storage conditions as specified in the Protocol in a secured area accessible only to authorised Personnel; and

(5) maintain complete and current records for all received, dispensed and returned Investigational Product.

7.3 When this Agreement ends, the Institution must promptly return (or destroy if requested by the Organisation, and provide evidence of such destruction) to the Organisation any unused Investigational Product.

8. PROVISION OF EQUIPMENT

8.1 The Organisation may provide the Institution and Principal Investigator with the Equipment; this will be at no charge. Unless otherwise agreed by the parties in writing, the Equipment will be used only by the Principal Investigator and Personnel involved in the conduct of the Study and only for the purposes of the Study.

8.2 The Institution will ensure the Principal Investigator and Institution's Personnel will use the Equipment in accordance with the Equipment's manufacturer's specifications and instructions.

8.3 The Institution will take reasonable care in the use and secure storage of the Equipment.

8.4 The parties will cooperate in maintaining the Equipment in good working order and ensuring that it is in a safe condition and compliant with the requirements of the relevant licensing and safety authorities so long as it continues to be used for the purposes of the Study. The parties will share equally any out of pocket expenses in doing so.

8.5 When this Agreement ends, if requested by the Organisation the Institution must return the Equipment to the Organisation or dispose it in an appropriate manner. If the Organisation makes no such request within 7 days after the Agreement ends, the Institution will be deemed to be the owner of the Equipment and may use it in any manner it wishes.

9. CONFIDENTIALITY AND PRIVACY

9.1 Subject to **clause 9.2**, the Parties must not, and must ensure their Personnel do not, use or disclose any Confidential Information, other than where and only to the extent such use or disclosure is necessary for the performance of the Study.

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

(1) for the purposes of complying with the Institution's internal complaint procedures, accident reporting procedures, quality assurance activities, disciplinary procedures or any applicable policy in relation to patient safety, Adverse Events and/or reportable incidents;

(2) for the purposes of disclosing any material risks identified during the Study or subsequent to it, to Study Subjects, Principal Investigators, medical practitioners administering treatment to Study Subjects, Responsible HRECs and Regulatory Authorities;

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

(4) for the purposes of the monitoring of the Study by the Responsible HREC;

(5) where the Organisation consents in writing to the disclosure;

(6) where the Confidential Information has been independently received from a third party who is free to disclose it;

(7) where the Confidential Information has entered the public domain other than as a result of a breach of this Agreement;

(8) as part of a publication issued under the provisions of **clause 11**;

(9) where release of the Confidential Information is required by law, with notice as soon as reasonably practical to the Organisation;

(10) for the purposes of legal advice; and

(11) disclosure to the Institution's insurer.

9.3 Where Confidential Information is disclosed in accordance with **clause 9.2(1)** or **9.2(4)**, 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.

9.4 The parties are responsible for ensuring that their Personnel are aware of the obligations in respect of Confidential Information in this **clause 9**, and are bound in similar terms to keep such information confidential, but are not responsible if those Personnel deliberately and intentionally fail to observe those restrictions.

9.5 The parties must ensure that any Personal Information arising from the Study regarding Study Subjects or Personnel, is collected, stored, used and disclosed in accordance with the Relevant Privacy Laws.

10. LIABILITY AND INSURANCE

10.1 Each party is liable for its acts and omissions in relation to the conduct of the Study.

10.2 Each party must maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the Study or performing its obligations under this Agreement.

10.3 The Institution satisfies the requirements of clause 10.2 if it is entitled to indemnity under a program or scheme of insurance or indemnity that is arranged by a department or agency of a State or Territory of the Commonwealth of Australia.

11. PUBLICATIONS

11.1 The Institution, the Principal Investigator and other Institution Personnel involved in the Study have the right to Publish the methods, results of, and conclusions from, the Study, subject to this clause and in accordance with copyright law.

11.2 The Institution must give notice of any proposed Publication drafted by it or any of its Personnel involved in the conduct of the Study to the Organisation at least 30 days before seeking to Publish same.

11.3 The Organisation may, within that 30-day period do any 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) If the Organisation can reasonably demonstrate that it has proprietary rights that may be affected by the Publication and which require protection, request delay of the Publication for no more than 60 days to allow the Organisation to file patent applications or take other measures to preserve those proprietary rights, in which case the Institution must abide by that request.

(3) Request that the discloser remove specified Confidential Information of the Organisation 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 Organisation.

11.4 If the Institution has not received any comments from the Organisation within 30 days of giving notice to the Organisation under clause 11.2, the Institution may proceed to make the Publication.

11.5 If the Organisation has provided any funding for this Study under clause 6, if requested by the Organisation the Institution must acknowledge the Organisation's support of the Study in a Publication.

11.6 The Institution is not required to give notice to the Organisation if it or any of its Personnel use or present any information concerning the methods, results of, and conclusions from, the Study for the purposes of internal training, education, evaluation or discussion.

12. STUDY RESULTS AND INTELLECTUAL PROPERTY

12.1 This Agreement does not affect the rights of any party to its respective Background Intellectual Property. For the purposes of carrying out the Study, the Organisation grants to the Institution a non-exclusive, perpetual, royalty free licence to use (including the right to sub-licence) the Organisation's Background Intellectual Property.

12.2 All Intellectual Property in the Study Materials will vest automatically upon its creation in the Organisation and the Institution presently assigns to the Organisation all existing and future Intellectual Property rights (including all future copyright) contained in the Study Materials. 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 Organisation's expense.

13. TERM AND TERMINATION

13.1 This Agreement commences from 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 Organisation or Institution. In the ordinary course of events this Agreement terminates when the Organisation makes its final payment to the Institution.

13.2 Either the Organisation or the Institution 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 Protocol (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 19.3**.

13.3 In addition to **clause 13.2**, a party may terminate this Agreement immediately by written notice to the other party if it believes on reasonable grounds that:

(1) continuing the Study poses an unacceptable risk to the rights, interests, safety or well-being of Study Subjects; and

(2) terminating this Agreement is the most appropriate way to respond to that risk.

13.4 The Organisation may terminate this Agreement with 30 days prior written notice to the Institution. In the event of such early termination, the Organisation will pay the reasonable costs of the Institution relating to the Study calculated in accordance with Schedule 2.

13.5 Either party may terminate the Agreement by giving 30 days prior written notice to the other in the circumstances described in clause 4.1(1).

13.6 In the event of termination, the Institution must promptly initiate all appropriate action to close the Study and, subject to any applicable retention requirements imposed by law, return to the Organisation (or destroy if requested by the Organisation, and provide evidence of such destruction) any completed Case Report Forms and other materials received from the Organisation before Study Completion.

13.7 In the event of termination the Institution must take all appropriate action to close out the Study Site in a timely manner.

13.8 In the event of early termination, the Organisation will cooperate with the Institution to ensure that Study Subjects who may be affected by termination receive adequate medical care. This may include the provision of Investigational Product in certain circumstances at the Organisation's expense.

13.9 The following provisions survive termination of this Agreement, **clauses 1, 4.1(3), 4.1(5), 9, 10, 11, 12, 13, 14, 15, 16 , 21 and 23**.

14. DISPUTES

14.1 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**").

14.2 If the dispute is not resolved within the Initial Period, then the dispute shall be referred within a further 28 days to the Australian Commercial Disputes Centre for mediation or any other agreed venue which conducts mediation. The parties will by agreement appoint a mediator to mediate the dispute in this forum. If the parties cannot agree to a mediator, then the mediator will be nominated by the then current President of the Law Society of the State or Territory in which the Institution

is located. Any documents produced for the mediation are to be kept confidential and cannot be used except for the purpose of settling the dispute.

14.3 Each party must bear its own costs of resolving a dispute under this clause, and unless the parties otherwise agree, the parties to the dispute must bear equally the costs of the mediator.

14.4 In the event that the dispute is not settled at mediation within 28 days (or such other period as the parties agree in writing) after the appointment of the mediator, or if no mediator is appointed, then within 28 days of the referral of the dispute to mediation, then the parties are free to pursue any other procedures available at law for the resolution of the dispute.

15. APPLICABLE LAW

This Agreement will be governed by, and construed in accordance with, the law for the time being in force in the State or Territory in which the Institution is located and the parties submit to the jurisdiction of that State or Territory and courts entitled to hear appeals from those courts.

16. NOTICES

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

(1) delivered to the party's address;

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

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

16.2 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;

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

(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.

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

17. WAIVER

17.1 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.

17.2 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.

18. VARIATIONS

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

19. ASSIGNMENT

19.1 Subject to **clause 19.2**, a party may not assign its rights or obligations under this Agreement without the prior written consent of the other party, such consent not to be unreasonably withheld.

19.2 A party may assign the benefit of this Agreement necessitated by the merger or sale of all or substantially all of its assets, provided it obtains from the relevant assignee a written undertaking in favour of the other party to be bound by the terms of this Agreement.

19.3 If a party assigns this Agreement under **clause 19.2,** and the relevant assignee is determined by the non-assigning party, in its discretion, as unsuitable to perform its obligations under this Agreement, that party may terminate the Agreement in accordance with **clause 13.2(3)**.

20. SUBCONTRACTING

20.1 The Organisation may subcontract any of its obligations under this Agreement, save for the obligations set out in **clause 10** of the Agreement. The Organisation remains responsible for all subcontracted obligations and is liable for all acts and omissions of any subcontractor as if they were the Organisation's acts and omissions. In the event that the Organisation subcontracts with another party to perform any of the Organisation's obligations under this Agreement, the Organisation is bound by and will observe its obligations under **clause 9.1** in its dealings with the subcontractor.

20.2 No subcontractor will have any rights under this Agreement against the Institution or be entitled to receive any payment from the Institution.

21. ENTIRE AGREEMENT

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

22. 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 the Agreement.

23. 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.

24. FORCE MAJEURE

If any party is delayed or prevented from the performance of any act required under the 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, performance of such act shall be excused for the period of such event provided that if such interference lasts for any period in excess of 30 days each party may, by written notice to the others, terminate this Agreement.

25. PRIORITY

25.1 In the event of an inconsistency, this Agreement is to be interpreted in accordance with the following order of priority:

(1) first, by reference to the Schedules;

(2) second, by reference to the terms of this Agreement (other than those set out in the Schedules);

(3) finally, by reference to the Protocol.

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

Signed on behalf of the **Organisation**

Signed: T. Swift

Name: Dr. Tracey Swift
Director Research Management

Position: T.S

Date: 13 · 5 · 2014

Signed on behalf of the **Institution**

Signed:

Name: Dr Mark Salmon

Position: EOMS

Date: 23/9/14
for and on behalf of the Director General of Health as delegate of the Minister for Health

The Principal Investigator acknowledges this Agreement and understands the obligations it imposes

Acknowledged by the **Principal Investigator**

Signed:

Name: IAN DICKINSON

Position: Professor Maternal Fetal Medicine

Date: 26.7.14

Schedule 1
Key Information
(to be inserted by Organisation)

Study Name:	STRIDER NZAus
Study Site/s:	King Edward Memorial Hospital, Perth
Target number of Study Subjects:	Minimum: 5 Maximum: 30 Recruitment is competitive, to a total of 122 participants.
Recruitment Period:	Start: 01/06/2014 End: 31/08/2016, or once 122 participants total have been recruited to the trial.
Principal Investigator Name:	Professor Jan Dickinson
Address:	374 Bagot Road, Subiaco Perth State:WA P/code: 6008
Responsible HREC:	Women and Newborn Health Service Ethics Committee
Equipment Provided by Organisation:	Study folder containing trial protocol and other essential trial documents to support conduct of STRIDER NZAus at the Institution. Consumables including CRFs, study participant materials, pens and post-it notes. **Investigational Product:** Oral sildenafil citrate 25mg tablets or matching placebo tablets containing no active ingredient.

Schedule 2
Payments

	NZD
Set up fee (once only at Institution activation)	1000
Payment per Study Participant	1000

The Study is funded under an agreement between the Health Research Council of NZ and the Organisation. The Organisation has no obligation to pay for Study Participant(s) after the Organisation has advised the Institution with notice in writing that funding support for the Study has been used except for any non-cancellable costs in accordance with clause 6.4.

The Organisation will make the per participant payments based on invoices by the Institution on a six (6) monthly basis as the study progresses. The Organisation will pay the Institution on receipt of an invoice addressed as below. The Organisation will make payment on the 20th of the month following date of invoice.

Invoicing address:
The University of Auckland
Private Bag 92019
Auckland 1142

Notwithstanding clause 6.1 all payments are in New Zealand Dollars (NZD) and are inclusive of any applicable GST. The Organisation will not be liable for any amount of tax that the Institution is required to pay.

Schedule 3
Study Protocol Identification

Full Title:	**STRIDER (NZAus):** A randomised Controlled Trial of **S**ildenafil **T**herapy **I**n **D**ismal Prognosis **E**arly-Onset Intrauterine Growth **R**estriction (New Zealand and Australia).
Version Number:	Version 4
Date:	December 2013
List of Key Arrangements:	.....

Schedule 4
Special Conditions