Author's response to reviews

Title: Environmental determinants of islet autoimmunity (ENDIA): a pregnancy to early life cohort study in children at-risk of type 1 diabetes

Authors:

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ENDIA Study Group (endia@adelaide.edu.au)
Leonard C Harrison (harrison@wehi.edu.au)

Version: 2  Date: 5 August 2013

Author's response to reviews: see over
Dear Catherine Olino,

Thank you for your email dated August 3rd 2013. In response to your questions:

Q. Could you please clarify whether you have ethical approval and external funding for your study, and if so, could you send evidence of your approvals to the address below?... We do require to see the approval from all centres involved in the study (all 6 in this instance)... it would be greatly appreciated if you could also clarify whether the funding mentioned was specifically for this study and whether the study protocol underwent full peer review to obtain this funding, and if so, to include proof of this funding.

A. I can confirm that we have both ethical approval and external funding for the study outlined in this protocol. The approval letters from the 6 HRECs that have reviewed this project are attached to this cover letter. This includes:
   - The Women’s and Children’s Health Network HREC
   - Melbourne Health HREC
   - Princess Margaret Hospital for Children HREC
   - Sydney Children’s Hospital Network HREC
   - St John of God Health Care HREC
   - Mater Health Service HREC

A. Funding specifically for this study is provided by a National Health and Medical Research Council (NHMRC) Project Grant. The NHMRC Project Grant scheme is peer-reviewed. In addition to the Outcome letter, which states at the top of page 2 the amount awarded was Au$1,083,720, the panel summary following the peer review process is attached.

Q. Could you also provide a list of any manuscripts that are under submission with other journals based on this study protocol?

A. There are no manuscripts under submission with other journals based on this study protocol.

Q. BioMed Central requires all controlled clinical trials to be registered in a suitable publicly accessible registry prior to consideration for publication. The trial registers that currently meet all of the ICMJE guidelines can be found at [http://www.icmje.org/faq.html](http://www.icmje.org/faq.html).

A. This study has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) with registration number ACTRN1261300794707. Registration with the ANZCRT is accepted by the ICMJE according to the information provided here: [http://www.icmje.org/faq_clinical.html](http://www.icmje.org/faq_clinical.html).

Yours sincerely,

Megan Penno
On behalf of the authors
10th April 2012

Prof J Couper
Endocrinology & Diabetes
WCHN

Dear Jenny

Re: Early environmental determinants of pancreatic islet autoimmunity: a pregnancy to early life cohort study in children at risk of type 1 diabetes. REC2456/2/15

I refer to your letter dated 26th March 2012 in which you responded to matters raised by the WCHN Human Research Ethics Committee at its February 2012 meeting. I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the National Statement on Ethical Conduct in Human Research.

I note your advice regarding the involvement of non-WCHN staff or students on the study. You are reminded that if now, or in the future, the study involves non-WCHN staff or students, a signed Confidentiality Agreement will be required and, if they visit any WCHN site or have access to identifiable patient information, a National Police Certificate provided to the Ethics Committee and the Human Resources Department. The study may proceed on this proviso.

I remind you approval is given subject to:
• immediate notification of any serious or unexpected adverse events to subjects;
• immediate notification of any unforeseen events that might affect continued ethical acceptability of the project;
• submission of any proposed changes to the original protocol. Changes must be approved by the Committee before they are implemented;
• immediate advice, giving reasons, if the protocol is discontinued before its completion;
• submission of an annual report on the progress of the study, and a final report when it is completed. Please note it is your responsibility to provide these reports – without reminder from the Ethics Committee.

Approval is given for three years only. If the study is more prolonged than this, an extension request should be submitted unless there are significant modifications, in which case a new submission may be required. Please note the approval number above indicates the month and year in which approval expires and it should be used in any future communication.
If University of Adelaide personnel are involved in this project, you, as chief investigator must submit a Human Research Approval notification form online at http://www.adelaide.edu.au/ethics/human/guidelines/ within 14 days of receiving this ethical clearance to ensure compliance with University requirements and appropriate indemnification.

Yours sincerely

[Signature]
TAMARA ZUTLEVICS (DR)
CHAIR
WCHN HUMAN RESEARCH ETHICS COMMITTEE
Melbourne Health Human Research Ethics Committee
Ethical Approval of a Research Project

Prof Peter Colman
Diabetes and Endocrinology
The Royal Melbourne Hospital
C/- The Post Office
PARKVILLE VIC 3050

11th April 2013

Dear Prof Colman,

MH Project Number: 2012.147

Project Title: Early environmental determinants of pancreatic islet autoimmunity: a pregnancy to early life cohort study in children at risk of type 1 diabetes

HREC Approval Date: 10th April 2013

I am pleased to advise that the above project has received ethical approval.

Participating Sites:

- Royal Melbourne Hospital

Approved Documents:

- Protocol Version 7.2 dated 14th January 2013
- Melbourne Health Participant Information and Consent Form – Genetic Study Adult Type 1 Diabetic Relative Providing Own Consent Version 4 dated 26th February 2013
- Melbourne Health Participant Information and Consent Form – Genetic Study Parent/Guardian Consenting of Behalf of a Child with Type 1 Diabetes Version 4 dated 26th February 2013
- Melbourne Health Participant Information and Consent Form – Non-Interventional Study Parent and Child Consent Version 4 dated 26th February 2013
- Melbourne Health Participant Information and Consent Form – Non-Interventional Study Pregnant Women and Child Version 6 dated 26th February 2013
- Pregnancy Physical Activity Questionnaire
- Maternal Lifestyle in Pregnancy Questionnaire Version Number 121009
- Maternal Lifestyle Postpartum Questionnaire Version Number 121009
- Serious Adverse Event (SAE) Report From Version Number 121113
- Guidelines for Maternal Urine Collection Version Number 121026
- Guidelines for Infant Urine Collection Version Number 121025
- Maternal Stool Collection Kit Version Number 121120 dated 20th November 2012
- Guidelines for Maternal Stool Collection Version Number 121120 20th November 2012
- Guidelines for Infant Stool Collection Version Number 121120 dated 20th November 2012

The Melbourne Health HREC operates and is constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007.
• Guidelines for Self-Collection of a Vaginal Swab Version Number 121120 dated 20th November 2012
• Guidelines for Breast Milk Collection Version Number 121120 dated 20th November 2012
• Guidelines for Colostrum Collection Version Number 121120 dated 20th November 2012
• Manual Expression of Milk Marmet Technique dated 27th October 2003
• Dietary Questionnaire dated 2005
• ENDIA Brochure
• ENDIA Poster
• Infant Feeding Diary – Birth to 6 Months

Site Specific Assessment:

Please note: You cannot commence this study until you have completed all the requirements of the Site Specific Assessment and have received the “Approval to Conduct a Research Project at Melbourne Health” certificate.

Conditions of Ethics Approval:

In order to comply with the National Statement on Ethical Conduct in Human Research 2007, Guidelines for Good Clinical Research Practice and Melbourne Health Research Policies and Guidelines you are required to:

• Submit a copy of this letter to the Radiation Safety Officer (RSO) at Melbourne Health, for addition of the project to the Licence for Research Involving Human Volunteers held by the Department of Human Services Radiation Safety Section Radiation Safety Licence (if your project involves exposure to ionising radiation). Note: You cannot commence the project until you have received notification from the RSO that the project has been added to the Licence;
• Notify the HREC of the actual start date of the project;
• Submit to the HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure;
• Notify the HREC of any adverse events in accordance with the Melbourne Health Guidelines for Monitoring and Reporting of Safety in Clinical Trials Involving Therapeutic Products and Other Clinical Research, July 2009;
• Notify the HREC of any unforeseen events;
• Notify the HREC of your inability to continue as Principal Investigator or any other change in research personnel involved in the project;
• Notify the HREC if a decision is taken to end the study prior to the expected date of completion or failure to commence the study within 12 months of the HREC approval date;
• Notify the HREC of any other matters which may impact the conduct of the project.

Reporting

You are required to submit to the HREC:

• An Annual Progress Report every 12 months (or more frequently as requested by the reviewing HREC) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report in a timely manner; and
• A comprehensive Final Report upon completion of the project.

The HREC may conduct an audit of the project at any time.
Please refer to the Office for Research website to access forms such as the Amendment Form, Annual Report/Final Report Form, Guidelines for Monitoring and Reporting of Safety in Clinical Trials Guidelines and Adverse Event Report Forms, and other information and news concerning research at Melbourne Health: http://www.mh.org.au/www/342/1001127/displayarticle/1001352.html

A list of those HREC members present at the review of this project can be obtained from the above website.

Yours sincerely,

Ms Angela Gray
Manager, Melbourne Health Human Research Ethics Committee
Ph: 9342 3006
E-mail: angela.gray@mh.org.au
A/Professor Tim Jones  
Department of Endocrinology and Diabetes  
Level 3  
Princess Margaret Hospital for Children  
Roberts Road  
SUBIACO WA 6008  

Dear Professor Jones  

REGISTRATION NUMBER:  1989/EP

TITLE:  Early environmental determinants of pancreatic islet autoimmunity: a pregnancy to early life cohort study in children at risk of type 1 diabetes

MEETING DATE:  17 May 2012

RGO and Ethics requirements satisfied 2 July 2012

The Princess Margaret Hospital for Children Ethics Committee and the Research Governance Office consider that the study protocol conforms to the requirements of the NHMRC Statement on Ethical Conduct in Human Research (National Statement) and resolved at the meeting to recommend the protocol for approval to the Chief Executive. This recommendation has been ratified by the Child and Adolescent Health Service.

The Ethics Committee does however wish to be informed immediately of:

I. any untoward effects experienced by any participant in the trial where those effects in degree or nature were not anticipated by the researchers, and steps taken to deal with these,

II. substantial changes in the research protocol together with an indication of ethical implications, and

III. other unforseen events.

The Ethics Committee has been charged with the responsibility of keeping the progress of all approved research under surveillance. A copy of the final result must be forwarded to the Committee upon completion of the research or if the research is not completed within twelve months you are asked to submit a progress report and annually thereafter. This information should include:
a) The status of the project (completed/in progress/abandoned/not commenced). In the event that a project does not commence within 12 months of being approved by the Ethics Committee, the study must be resubmitted to the Committee for approval.

b) Compliance with conditions of ethical approval, including security of records and procedures for consent.

c) Compliance with any special conditions stated by the Ethics Committee as a condition of approval.

d) Results from the study to date, including outcome.

Please note that approval for studies is for **three years** and if the research is not completed within that period of time, a request for an extension of time should be submitted for consideration. In the event that a project does not commence within **12 months** of being approved by the Ethics Committee, the study must be resubmitted to the Committee for approval.

In accordance with the NHMRC National Statement on Ethical Conduct in Human Research Chapter 5.5.3, researchers have a significant responsibility in monitoring and must submit the following to the Ethics Committee:

- Annual Reports on the anniversary of the approval date of the study
- Adverse event reports as received
- Amendments and extensions to the study to be requested in adequate time

Please quote the above registration number on all correspondence.

Yours sincerely

[Signature]

Dr Mark Salmon  
Executive Director  
Medical Services

2 July 2012

- The Ethics Committee is constituted, and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans
Contact for this correspondence:
Research and Development
Ethics & Governance Administration Assistant
Phone: (02) 9845 1253
Facsimile: (02) 9845 1317
Email: ethics.schn@health.nsw.gov.au

Corner Hawkesbury Road
and Hainsworth Street
Locked Bag 4001
Westmead NSW 2145
Sydney Australia
DX 8213 Parramatta
Tel +61 2 9845 0000
Fax +61 2 9845 3489
http://www.schn.health.nsw.gov.au
ABN 53 188 579 090

Prof Jennifer Couper
Endocrinology and Diabetes
Women’s and Children’s Hospital
North Adelaide
SA 5006

Dear Professor Couper,

HREC reference number: 12/SCHN/296
You must quote this number for all future correspondence

Project title: Early Environmental Determinants of Pancreatic Islet Autoimmunity: A Pregnancy to Early Life Cohort Stud in Children at Risk of Type 1 Diabetes.

NSW Sites listed: The Children’s Hospital at Westmead
Sydney Children Hospital at Renwick
St George Hospital
Westmead Hospital, Sydney
Royal Hospital for Women, Sydney
St George Hospital

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Sydney Children’s Hospitals Network Human Research Ethics Committee (HREC) at its meeting held on 14th September 2012. This HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council’s National Statement on Ethical Conduct in Research Involving Humans and the CPMP/ICH Note for Guidance on Good Clinical Practice.

I am pleased to advise that after receiving all outstanding items required for this project on 1/11/12, 12/11/2012, 24/01/2013, 05/02/13, 21/02/2013 and 8/03/2013, the HREC has granted ethical approval of this research project. **Your approval is valid from the date of this letter.**

This letter constitutes ethics approval ONLY. You may NOT commence at the public health sites specified in this letter until you receive site authorisation through a site approval letter from the research governance manager at each site. To receive site authorisation, you must submit a “Site Specific Application” or an “Access Request Form” to each site and await your site approval letter.

The documents reviewed and approved include:
J:\DATA\Research\PROJECT FILES - Ethics & Governance\Ethics\NEAF\2012\12SCHN296\Correspondence & emails\2013.03.01_12SCHN296_NEAF Draft letter.docx
<table>
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<th>Document</th>
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<td>15/08/2012</td>
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<td>7.2</td>
<td>14/01/2013</td>
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<td>Pregnancy Physical Activity Questionnaire</td>
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<td>Dietary questionnaire</td>
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<td>ENDIA brochure</td>
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<td>Guidance sheet for maternal urine collection</td>
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<td>Guidance sheet for infant urine collection</td>
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<td>Guidance sheet for self-collection of a vaginal swab</td>
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<td>Guidance sheet for colostrum collection</td>
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<td>Guidance sheet for breast milk collection</td>
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<tr>
<td>ENDIA Infant Feeding Diary</td>
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<td>03/10/2012</td>
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Please note the following conditions of approval:

1. Please provide signatures for the following investigators prior to taking part in the study:
   A/Prof Andrew Cotterill, Prof Len Harrison, Dr Alison Nankervis, Prof Jodie Dodd, Prof Fergus Cameron, Prof Grant Morahan and A/Prof John Wentworth.

2. Participant Information Sheets, under the heading ‘Who has reviewed the research project?’ replace the second sentence with the following Ethics complaints paragraph:

   **This project has been approved by The Children’s Hospital at Westmead Ethics Committee. If you have any concerns about the conduct of this study, please do not hesitate to contact the Secretary of the Ethics Committee (02 9845 3017) and quote approval number HREC/12/SCHN/296.**

3. Participant Information Sheets page numbers need to be in sequential order.

4. Participant Information Sheet for postnatal recruitment, page 2, under the sub-heading ‘What we ask of your child’, bullet point four, replace ‘prevent pain’ with ‘reduce pain’.
5. The co-ordinating investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
   - Unforeseen events that might affect continued ethical acceptability of the project.

6. Proposed changes to the research protocol, conduct of the research, or length of HREC approval, will be provided to the HREC for review in the specified format.

7. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

8. The co-ordinating investigator will provide an annual report to the HREC and at completion of the study. The annual report form is available on the Hospital’s intranet and internet or from the Secretary.

9. Your approval is valid for 5 years from the date of the final approval letter. If your project extends beyond five years then at the 5 year anniversary you are required to resubmit your protocol, according to the latest guidelines, seeking the renewal of your previous approval. In the event of a project not having commenced within 12 months of its approval, the approval will lapse and reapplication to the HREC will be required.

Should you have any queries about the HREC’s consideration of your project please contact the Ethics and Governance Administration Assistant on 9845 1253.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The HREC wishes you every success in your research.

Yours faithfully

Signature: [Signature]  Date: 12/3/2013

Dr Peter Cooper  
Chair,  
Sydney Children’s Hospitals Network Human Research Ethics Committee

cc: A/Prof Maria Craig, Institute of Endocrinology and Diabetes, CHW
13 February 2013

Professor Timothy Jones  
Dept of Endocrinology & Diabetes  
Princess Margaret Hospital  
GPO Box D184  
Perth WA 6840

Dear Professor Jones

Re: (ENDIA) Early Environmental Determinants of Pancreatic Islet Autoimmunity: A Pregnancy To Early Life Cohort Study In Children At Risk Of Type 1 Diabetes (Our ref. No. 592)

Thank you for forwarding the study for review by the St John of God Health Care Ethics Committee (“the Committee”).

The Committee understands that the majority of the study is being undertaken at Princess Margaret Hospital (PMH) including participant recruitment and followup with St John of God Health Care participation sought for only 2 stages of visits in the study.

I am pleased to advise that the Committee at its meeting on 13 February 2013, has granted ethical approval of the study as satisfying the ethical requirements outlined in the National Health and Medical Research Council’s (NHMRC) National Statement on Ethical Conduct in Human Research (2007) (“National Statement”). Please find attached a signed and dated Committee membership list.

I now confirm final approval for your project to be conducted at St John of God Murdoch Hospital (“the participating site”).

The Committee is a Human Research Ethics Committee that is constituted and operates in accordance with the National Statement. In line with the National Statement requirements, researchers need to keep the Committee and the institution (specifically, the participating site) promptly and regularly informed on the progress of their approved research including:

1. any adverse events or unexpected outcomes that may affect continued ethical approval of the program.
2. any proposed changes in the research protocol.
3. when the program is completed or abandoned.

.../2
The Committee would also appreciate receiving at a minimum an annual project progress report, as well as a final report on the project results and/or any subsequent publications.

I wish you well with your project.

Yours sincerely

Professor Con Michael
(as a delegate of St John of God Health Care)

Enc.

cc. Mr Wayne Soon, Dept of Endocrinology & Diabetes, PMH
cc. Mr Adam Coleman, DON, SJG Murdoch Hospital
MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

21st February 2013

Dr Andrew Cotterill
Paediatric Endocrinology
Mater Children’s Hospital
Raymond Terrace
South Brisbane 4101

Dear Dr Cotterill

Re: Protocol Ref # 1941C Environmental determinants of pancreatic islet autoimmunity: a pregnancy to early life cohort study in children at risk of type 1 diabetes

I write to advise that the Mater Health Services Human Research Ethics Committee considers the above study to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and has granted ethical approval for your research proposal. Please accept our very best wishes for the success of this study. In all future correspondence with the Committee please quote the Mater reference number.

Documents reviewed and approved include:

- Mandatory Cover Sheet Version 2, dated 15th January 2013
- NEAF Version AU1/51C0111, dated 17th January 2013
- Participant Information Sheet and Consent Form ENDIA, Adult Proband Mater Version 4, dated 19th February 2013
- Participant Information Sheet and Consent Form ENDIA, Child Proband Mater Version 4, dated 19th February 2013
- Participant Information Sheet and Consent Form ENDIA, for Postnatal recruitment Mater Version 4, dated 19th February 2013
- Participant Information Sheet and Consent Form ENDIA, Non-Interventional for Mother and Child Mater Version 6, dated 19th February 2013
- Study Questionnaires
- Pregnancy Physical Activity (Validated)
- Lifestyle in pregnancy questionnaire Version 121009, dated 6th October 2012
- DGESv2 (validated)
- Lifestyle postpartum questionnaire Version 121009, dated 9th October 2012
- Advertisements
- ENDIA brochure Version 121025, dated 25th October 2012
- ENDIA Poster Version 130116, dated 16th January 2013
• Participant Diary 0-6 Month Feeding Diary Version 121003, dated 3rd October 2012
• Participant Guidance Sheets
• Maternal urine Version 121106, dated 6th November 2012
• Infant Urine Version 121105, dated 6th November 2012
• Maternal Stool Version 121120, dated 20th November 2012
• Infant Stool Version 121120, dated 20th November 2012
• Vagina Version 121120, dated 20th November 2012
• Colostrum Version 121120, dated 20th November 2012
• Breast Milk Version 121120, dated 20th November 2012
• HREC approval letters from the WCHN and PMH HRECs for the conduct of ENDIA is SA and WA, respectively.
• Serious Adverse Event (SAE) Report Form Version 121113, dated 11th November 2012

This approval is valid until 21st February 2016. Please note the following conditions of approval.

• Any departure from the protocol detailed in your proposal must be reported immediately to the Committee.
• When you propose a change to an approved protocol, which you consider to be minor, you are required to submit a written request for approval to the Chairperson, through the Secretary. Such requests will be considered on a case by case basis and interim approval may be granted subject to ratification at the next meeting of the Committee.
• Where substantial changes to any approved protocol are proposed, you are required to submit a full, new proposal for consideration by the Human Research Ethics Committee.
• You are required to advise the Research Ethics Coordinator immediately of any complaints made, or expressions of concern raised, in relation to the study, or if any serious or unexpected adverse events occur.
• Under the NHMRC National Statement on Ethical Conduct in Research Involving Humans, research ethics committees are responsible for monitoring approved research to ensure continued compliance with ethical standards, and to determine the method of monitoring appropriate to each project. You are required to provide written reports on the progress of the approved project annually, the first report being due on 21st February 2014. (The Progress Report is located at http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx or can be accessed through the Mater Intranet, Applications, Research Register then under the project name or alternately can be emailed to you). Please inform the Committee of publications, presentations at Conferences, education and quality improvement outcomes from this study. The Committee may also choose to conduct an interim audit of your research.
• Please be aware that all study procedures including follow up of participants and data analysis should be completed within the approval time frame or an extension should be requested.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project until authorisation from the Research Governance Office has been obtained.
Please contact the Executive Director in the participating hospital/hospitals prior to commencing of the study. To access medical records, for the purpose of this study, please provide a copy of this approval letter to the Corporate Health Information Manager. I would also be grateful if you could confirm the date of commencement. (All correspondence should be directed to the Mater Research Ethics Coordinator.)

Yours sincerely

[Signature]

A/Prof Andrew Crowden
Chairperson
Mater Health Services Human Research Ethics Committee
In reply please quote: NHMRC Project Grant Application APP1025083

Professor Jennifer Couper
Endocrinology and Diabetes
Womens and Childrens Hospital
North Adelaide SA Australia 5006

Dear Professor Couper

NHMRC Project Grant Application: APP1025083
Scientific Title: Early Environmental Determinants Of Pancreatic Islet Autoimmunity: A Pregnancy To Early Life Cohort Study In Children At Risk Of Type 1 Diabetes

I am pleased to advise that the Minister for Mental Health and Ageing, the Hon Mark Butler MP, has approved funding for your National Health & Medical Research Council (NHMRC) Project Grant to commence in 2012.

This letter provides you with important information about how to accept the offer of funding, the final approved budget within this offer and the Assessment Summary of your application.

Accepting this offer
The formal offer of grant funding for your application will be made under the NHMRC Funding Agreement between the Australian Government and your Administering Institution (the Funding Agreement). Your Administering Institution is responsible for informing you about the requirements of the Funding Agreement, including the amount and duration of funding, conditions or milestones, co-funding and reporting requirements.¹

Your Institution has until 31 January 2012 to advise NHMRC of your acceptance or the offer may be withdrawn.

Before payments for this grant commence, your Research Administration Office must provide NHMRC with notification that all clearances required for the research to commence, have been obtained. If you wish to accept the offer of funding, or have any queries, please contact your Research Administration Officer (RAO).

¹ A copy of the Funding Agreement is available at http://www.nhmrc.gov.au/grants/administering-grants/nhmrc-funding-agreement
Approved Budget

The approved budget for this Project Grant is $1,083,720.00 over a period of 3 years. This budget was determined by the Grant Review Panel (GRP) during its assessment of the application. You should note that this budget (excluding any equipment component) is provided as a one-line grant and grantees may expend the funds as necessary to support the research project provided that:

1. grant funds are applied only to achieve the approved research objectives of the grant;
2. all expenditure is in accordance with the requirements of the Funding Agreement, noting that use of funding for some purposes is expressly excluded in the Funding Agreement;
3. all expenditure complies with the Guidelines for Direct Research Costs (see funding_policy_2012.pdf)
4. funding approved for specific pieces of Equipment is used for this purpose;
5. funding is not used to provide infrastructure that should be provided by the institution; and
6. annual financial reports itemise expenditure against outgoings, including Salaries, Equipment and Direct Research Costs.

We will shortly provide a Schedule to the Funding Agreement, which will include a breakdown of the GRP-agreed budget.

Outcome of the Assessment

The Grant Review Panel (GRP) Assessment Summary provides information about your application’s ranking, relative to that of other applications, as assessed by the GRP. Detailed descriptions of the Category Scores are available in the NHMRC Project Grants Funding Policy for funding commencing in 2012 (the Funding Policy) available at funding_policy_2012.pdf and in the NHMRC Project Grant Peer Review Guidelines for funding commencing in 2012 available at peer_review_guidelines_nhmrc_2012.pdf.

Participation in NHMRC Peer Review

This year’s assessment process for Project Grants involved approaching more than 18,000 members of the research community, in addition to the work of the GRPs. NHMRC is grateful for this enormous contribution and will acknowledge it through our website’s peer review honour roll.

NHMRC is now moving towards the opening of the Project Grant round for funding commencing in 2013. To ensure that every application in that round has the best probability of two external assessments, we are reminding everyone that holds an NHMRC grant of their obligation to contribute to the peer review process, as set out in Clause 23.1 of the Funding Agreement, which states:

“…the Administering Institution must make available to NHMRC, free of charge but subject to NHMRC providing reasonable notice to the Administering Institution, the services of Specified Personnel to provide professional input into reviewing or assessing applications made under a Scheme in the Personnel’s area of expertise, as required by NHMRC. Each Specified Person may be required to review at least five (5) of Scheme applications each calendar year.”

As a Chief Investigator, we ask that you maintain your CV/Profile information up to date in RGMS to assist our identification of appropriate peer reviewers.

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Thank you for commitment to Australia’s health and medical research system. We wish you success in your future endeavours.

Yours sincerely

[Authorised for Electronic Transmission]

Virginia Hart
Executive Director
Research Programs Branch
17 October 2011

ENC: GRP Assessment Summary
APP1025083 GRP Assessment Summary

Your 2011 Project Grant application was scored as Category 6 following its review by expert peers.

Table 1 summarises the assessment of your application against the Project Grant Assessment Criteria. Table 2 summarises the proportion of 2011 Project Grant applications in each Category.

**Table 1:** Summary of scores for your application in relation to the assessment criteria, and overall Category score. Criteria scores are the GRP mean. The Category score is calculated from the weighted criteria scores.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Scores for APP1025083</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Quality – 50%</td>
<td>5.67</td>
</tr>
<tr>
<td>Significance and/or Innovation – 25%</td>
<td>5.00</td>
</tr>
<tr>
<td>Track Record – 25%</td>
<td>5.83</td>
</tr>
<tr>
<td>Category</td>
<td>6</td>
</tr>
</tbody>
</table>

**Table 2:** Summary of all assessed 2011 Project Grant applications by overall Category, including the mean for each criterion ± 1 standard deviation.

<table>
<thead>
<tr>
<th>Category</th>
<th>Number and Proportion (%) of applications in Category</th>
<th>Mean Scientific Quality</th>
<th>Mean Significance and/or Innovation</th>
<th>Mean Track Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>3 (0.1%)</td>
<td>6.59 ± 0.30</td>
<td>6.54 ± 0.39</td>
<td>7.00 ± 0.00</td>
</tr>
<tr>
<td>6</td>
<td>292 (8.4%)</td>
<td>5.73 ± 0.26</td>
<td>5.69 ± 0.33</td>
<td>5.88 ± 0.45</td>
</tr>
<tr>
<td>5</td>
<td>1312 (37.5%)</td>
<td>4.69 ± 0.42</td>
<td>4.85 ± 0.45</td>
<td>5.30 ± 0.52</td>
</tr>
<tr>
<td>4</td>
<td>1730 (49.5%)</td>
<td>3.79 ± 0.39</td>
<td>4.15 ± 0.42</td>
<td>4.71 ± 0.60</td>
</tr>
<tr>
<td>≤3</td>
<td>158 (4.5%)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>