ResearchMaster

Human Ethics Application

Application ID :	ETH16-0841
Application Title :	Development of an efficient test for autoimmune disease using gold nanoparticles
Date of Submission :	N/A
Primary Investigator :	Dr Olga Shimoni; Chief Investigator
Other Investigators :	Prof Michael Wallach; Co-Supervisor
	Mrs Anantdeep Kaur; 5Research Student

Section 1: Ethics Portal

Select your application type

What type of application are you looking for?
Please **do not** change your application type without first consulting with the Ethics Secretariat (9514 9772).

- (●) New application (including scope-checking for nil/negligible risk research)
- ( ) Ratification of existing approval
- ( ) Transfer of existing approval
- ( ) Evaluation of teaching and learning activities
- ( ) Amendment to existing approval
- ( ) Program approval

**You have selected 'new application (including scope checking for nil/negligible risk research)'.
This option allows you to create a new form and will check if you
application can be approved by the Faculty or whether it requires full ethics approval by the HREC. Please click save before continuing.**

What should I know before I start?

You have been redirected to the Nil/Negligible Risk Declaration Form.

Would you like more information on:

- ( ) This system
- (●) The ethics process
- ( ) Purpose of the ethics review process

The ethics process

You can find a flowchart of the Expedited Review Committee ethics application process on our website.

When you click on `submit' (found under the 'Action' tab on the left-hand side of this page) your application will automatically be submitted to the Ethics Secretariat who will then forward the application to the Expedited Review Committee.

Note: References to relevant sections of the National Statement (NS) and the Australian Code for the Responsible Conduct of Research (The Code) have been included as a guide in this form.

All research being conducted at UTS (funded or unfunded) requires the completion of the Research Information Form. Contact your Faculty Research Administrator or the Research and Innovation Office for more information on this form.

We would like to collect your feedback at the end of this form, including how long it took to complete. Your comments and feedback will help shape this form and the roll out of the remaining ethics forms.

Further information
If you have any questions or problems completing the form please contact the **Ethics Secretariat** or call **(02) 9514 9772**

Section 1A: Risk evalution

Determining the level of risk

You can save your application at any time by clicking on the save button on the left hand side in the toolbar.
Further examples and information to help you successfully complete your application can be found here

Please refer to the UTS HREC criteria for determining level of risk for assistance in determining the level of risk.

Please answer each question carefully and thoughtfully.
If you need to contact the Research Ethics Officer you can call (02) 9514 9772 or you can email the Research Ethics Officer

Does your research involve:

Collecting identifying information from participants*

- ( ) Yes
- (●) No

Direct interaction between researcher/s and participants*

- ( ) Yes
- (●) No

Any significant alternation to the routine care or service provided to participants*

- ○ Yes
- ◉ No

Any risks for participants beyond that experienced in their everyday activities*

- ○ Yes
- ◉ No

Participation by a member of any vulnerable group, other than incidental REF NS Chapter 4 *

- ○ Yes
- ◉ No

Randomisation or the use of a control group or a placebo*

- ○ Yes
- ◉ No

Infringing the rights, privacy or professional reputation of participants*

- ○ Yes
- ◉ No

Access or establishing a register or database which will be maintained after the completion of the research*

- ○ Yes
- ◉ No

Do you consider your research to be nil/negligible risk?*

- ◉ Yes
- ○ No

Please explain why your consider your research to be negligible risk (4000 character limit)*

The human samples (saliva and serum) being tested in the project will be obtained from another institution (Walter and Eliza Hall Institute of Medical Research, Melbourne) with which a Non Disclosure Agreement has already exists. Small volumes of the serum and saliva samples will be taken to validate the test developed using gold nanoparticles. There is no direct intervention with human participants or changes of treatment protocols, distress, interventions and does not involve issues of privacy or ethical issues.

The system has assessed your research as being nil/negligible risk research. The nil/negligible risk process is split into two parts; checking that your research is negligible risk by the system, and completing the Nil/Negligible risk form for endorsement by your Faculty. You will now need to complete some basic project information (such as project title and personnel) and follow the "Next Steps" instructions at the end of this form to continue to the nil/negligible risk declaration form.

Please continue to the next page

Section 2: Project information

Project title

You can save your application at any time by clicking on the save button on the left hand side in the toolbar.
For further information and help in completing your application go to Staff Connect

Declaration of Nil/Negligible Risk Research Form

Project Title*

Development of an efficient test for autoimmune disease using gold nanoparticles

Please note that the HREC is now granting a standard approval period for the research proposals.
The approval period for your project will be specified in your approval letter.
Please also note that research should not commence until ethics approval has been granted. The Committee cannot grant retrospective approval for data that has already been collected.

Ethics category code*

Human

Is this a pilot study?*

◉ Yes
○ No

If this is a pilot study or 'scoping' study, you may need to apply for full HREC approval at a later date if your methodology is no longer negligible risk

Please save and continue to the next page

Project personnel

You can save your application at any time by clicking on the save button on the left hand side in the toolbar.
For further information and help in completing your application go to Staff Connect.

Are there external or non-UTS investigators or personnel listed on this application?

○ Yes
◉ No

Is this a student project for a current degree course?*

◉ Yes
○ No

**NOTE: Under 'Position', additional Chief Investigators should be listed as '1Chief Investigator',
Co-Investigators should be listed as '3Assoc. Investigator' and students should be listed as '5Research Student.
Further options are available for Research/Project Managers and Administrators. The main contact should be marked as 'primary'**

If any details are incorrect or missing please contact the Ethics Secretariat on (02) 9514 9772 or by email.

How to add a person to the personnel table:
1. Click on 'More criteria' which is located on the top right hand corner of the table below
2. Enter the surname (and given name if the surname is common) in the fields marked 'Surname' and 'Given name' and click 'Search'
3. Click on the name of the person you wish to add
4. If they are the primary contact (e.g. Chief Investigator/Supervisor), tick "Yes" under 'Primary contact'
5. Select the position from the drop-down list (e.g. Chief Investigator/Research Student)
6. Click on the green tick

Internal personnel listed on this ethics protocol:
*

1	Primary	Yes
	ID	120275
	Surname	Shimoni
	Given Name	Olga
	Name	Dr Olga Shimoni
	Position	Chief Investigator
	Type	Internal
	AOU	SCI.School of Mathematical and Physical Sciences
	Managing Unit	Science
	Email Address	Olga.Shimoni@uts.edu.au
	Contact Phone	2842
2	Primary	No
	ID	021128
	Surname	Wallach
	Given Name	Michael
	Name	Prof Michael Wallach
	Position	Co-Supervisor
	Type	Internal
	AOU	SCI.School of Life Sciences
	Managing Unit	Science
	Email Address	Michael.Wallach@uts.edu.au
	Contact Phone	4082
3	Primary	No
	ID	11611629
	Surname	Kaur
	Given Name	Anantdeep
	Name	Mrs Anantdeep Kaur
	Position	5Research Student
	Type	Student
	AOU	SCI.Faculty of Science
	Managing Unit	Science
	Email Address	Anantdeep.Kaur@student.uts.edu.au
	Contact Phone	

If you cannot find a person through the personnel table(s) above, please enter their details here (title, name, organisation, department, phone number, address, email address and their position on this protocol). If the person you cannot find is EXTENRAL to UTS please contact the Ethics Secretariat
(4000 character limit)

This question is not answered.

Please provide additional (or preferred) contact details of any of the people listed on the project if necessary.

This question is not answered.

Please provide details of any formal qualifications (REF NS 1.1(e)) of each person listed on the project.*

Prof Michael Wallach, PhD
Associate Head of School, UTS

Dr Olga Shimoni, PhD
Senior Lecturer, UTS

Anantdeep Kaur
Masters in Medical Biotechnology, UTS (Completed)
PhD Science , UTS (currently enrolled)

Please outline the experience of each person listed on this project relevant to this application.*

Prof Michael Wallach has extensive experience both in academic and industrial science. For this project in particular he has helped to design the protocols and experiments to carry the immunology studies.
Dr Olga Shimoni focuses on the development of novel multi-functional nanoparticles for the applications in bio-medicine.
Anantdeep Kaur is a second year PhD student working on this project.

Primary AOU*

SCI.Faculty of Science

Please save and continue to the next page

Student details

You can save your application at any time by clicking on the save button on the left hand side in the toolbar.
For further information and help in completing your application go to Staff Connect.

Degree being undertaken*

PhD Science
Course Code: C02031
Project Title: Development of an efficient test for autoimmune disease using gold nanoparticles

Have you been successful in your doctoral/masters assessment? *

- (●) Yes
- ( ) No

Please save and continue to the next page

Funding details

You can save your application at any time by clicking on the save button on the left hand side in the toolbar.
For further information and help in completing your application go to Staff Connect.

Have you received funding in relation to this research?*

- ( ) Yes
- (●) No

Do you intend to apply for funding in the future?*

- ( ) Yes
- (●) No

Please continue to the next page

Section 3: Research summary

Description

You can save your application at any time by clicking on the save button on the left hand side in the toolbar.
For further information and help in completing your application go to Staff Connect.

Please provide a brief description of the research design including research questions and proposed methods for conducting the research (approximately 250 words)*

Autoimmune disease sufferers are a sizable and growing market with diseases such as coeliac disease showing 'iceberg characteristics', with a large population of un-diagnosed cases. Coeliac disease is a complex chronic disorder that primarily damages the small intestine. The current methods for diagnosis for coeliac disease are based on serum testing of antibodies using ELISA and skin prick testing which are invasive, expensive and lab based requiring experts for usage.
This project will help in the development of a diagnostic device that uses antibodies in serum and saliva as biomarkers. Proteins such as gliadin or their related peptides will be adsorbed on the surface of gold nanoparticle. The aggregation of gold nanoparticles in the presence of antibodies will lead to a colour change from pink red to violet blue and would indicate a positive test, indicating presence for the disease. The test would be easy to use, cheap and non-invasive.

What are the hypotheses/goals/aims/objectives of your research?
Please include a brief description using plain English explaining your research aims (approximately 100 words)
*

The main goal of the project is to develop a non-invasive diagnostic test for autoimmune disease such as coeliac disease based on gold nanoparticles. The specific objectives include:
1. To develop methods for the binding and adsorption of autoimmune disease causing proteins such as gliadin and their related peptides on the surface of gold nanoparticles.
2. To validate the adsorption of the autoimmune proteins and peptides on the surface of the gold nanoparticles by using methods such as transmission electron microscopy (TEM) and dynamic light scattering (DLS).
3. To test the feasibility and specificity of interaction between gold nanoparticles and antibodies for use in diagnosis of diseases.
4. To test and validate the developed test on real patient serum and saliva samples.

What do you hope the outcome(s) of this research will be?*

This project would help in the development of a non-invasive diagnostic device which will be non-invasive, cheap and have high levels of sensitivity and specificity.

Who do you think will benefit from this research?*

The research would help in easy diagnosis of coeliac disease in all sufferers particularly in children as it will be a non-invasive diagnostic test which is quick and easy to use.

Please save and continue to the next page

Additional details

You can save your application at any time by clicking on the save button on the left hand side in the toolbar.
For further information and help in completing your application go to Staff Connect.

Will you be involving an external institution, organisation or community group?*

- (●) Yes
- ( ) No

Please provide details*

Human serum and saliva samples will be obtained from The Walter and Eliza Hall Institute of Medical Research, Parkville, Victoria, with which a Non-disclosure agreement already exists.

Will this research gather information from participants? (E.g. surveys, questionnaires, interviews, etc)*

- ( ) Yes
- (●) No

Will you be obtaining consent from participants?*

- ( ) Yes
- (●) No

Please continue to the next page

Section 4: Checklist

Attachments

You can save your application at any time by clicking on the save button on the left hand side in the toolbar.
For further information and help in completing your application go to Staff Connect.

An attachment table will appear once you have answered yes to any of the questions below.

I have attached the following supporting documents

Doctoral or Masters assessment*

- (●) Yes
- ( ) N/A

Participant Information Sheet(s)*

- ( ) Yes
- (●) No

Informed Consent Form *

- ( ) Yes
- (●) No

Evidence of approval from external institution, organisation or community group*

◉ Yes

○ N/A

Please explain why any of the above have not been attached (either softcopy/hardcopy) and if applicable, when they will be provided.
*

This research project does not involve any direct interaction with any of the participants. Therefore, participant information sheets and the consent form have not been attached.

Documents attached to this application
NOTE: If you are only attaching a hardcopy of any attachments relating to this application, you must still click on 'Additional Attachments' on the right hand side of the table. Click on the help button for more details.
*

Description	Reference	Soft copy	Hard copy
Evidence of approval from external institute	2003.009 18 July 2016 HREC Approval 18.07.2016.pdf	✓	
Evidence of approval from external institute	2003.09 Ethics Approval - Original submission.pdf	✓	
Stage 1 Doctoral Assessment	Stage 1 assessment.pdf	✓	

I understand that I need to submit this application form to my Faculty Research Office*

◉ Yes

○ No

Please save and continue to the next page

Declaration

Declaration Signoff

I declare that the information I have given above is true and that this research does not contravene the National Statement on Ethical Conduct in Human Research, the Australian Code for the Responsible Conduct of Research, and relevant UTS policy and guidelines relating to the safe and ethical conduct of research.

I also declare that I will respect the personality, rights, wishes, beliefs, consent and freedom of the individual participant in the conduct of my research and that I will notify the UTS Human Research Ethics Committee of any ethically relevant variation in this research.

In signing this declaration, I confirm that this form has been distributed to each member of the research team, and they have agreed to abide by the principles and processes of the research as outlined in this form.

I also declare that I believe this research to be nile/negligible risk for the reasons outlined in this form, and that my research does not require approval from the UTS Human Research Ethics Committee

Declaration Signoff*

1	Full Name	Dr Olga Shimoni
	Position	Chief Investigator
	Declaration signed?	No
	Signoff Date	
2	Full Name	Mrs Anantdeep Kaur
	Position	5Research Student
	Declaration signed?	Yes
	Signoff Date	29/09/2016

Please note that the Faculty cannot review your Declaration of nil/negligible risk research without first having received a signed hardcopy
I have obtained and attached signatures to this declaration form:

◉ Yes

○ N/A

This question is not answered.

Faculty review

Please note that this section should be signed off by the Faculty after being printed.
Please continue to the next page to electronically submit your application.
You can submit the hardcopy of this form after submitting it electronically

Faculty review - Associate Dean (Research) or nominee

I am aware that this research is being conducted within this faculty and am satisfied that the researchers have met faculty requirements in relation to this research, and that this research is low or negligible risk.

Signature of Associate Dean (Research) or nominee (Please sign once printed):

M.S

This question is not answered.

Date:

4/10/16

This question is not answered.

I ~~do/do not~~* do not wish to add comments in relation to this application (*please circle which one when signing the hard copy):

This question is not answered.

How do I submit this form?

Submission instructions

Your application has been assessed by the system as being nil/negligible risk and can be submitted to your Faculty for review.

Please ensure that you sign the form and submit.

All questions marked with a red asterisk (*) must be answered before submitting this form. Please check that all pages in the form menu (located on the left of this page) have a green tick.
Pages marked with a (!) indicate that one or more mandatory questions have not been answered.

To electronically submit your application
Please click on the `save' button in the toolbar before clicking on the Action tab which is located on the left of this page next to the form tab.
Click on 'Submitunder the action tab to submit your application.
If you are a student, this form will automatically go to your supervisor for review. Your supervisor will have two options:

1. Submit to the Faculty or
2. Request further information or changes from you prior to submitting to the Faculty.

You will receive an email notification if your supervisor has requested further information or changes, or whether your application has been submitted to the Ethics Secretariat.

To physically submit your application
The Faculty cannot review this form without first having received a one signed copy. Please submit a copy to your Faculty for sign off by the Associate Dean Research (ADR) or nominee.
You can contact the Ethics Secretariat if you are unsure of who to submit this form to.

Please ensure you save a copy of this form before submitting to the Faculty as
access to this form will be restricted until after the Faculty has reviewed your declaration.

What happens next?

What happen's next?

Have you signed and submitted this form for your supervisor and Faculty (ADR) to review?

- (•) Yes
- ( ) No

This question is not answered.

Once you click on submit, this form will be electronically submitted to your supervisor for review before going to the Faculty for review.
If your supervisor has any comments, they will be able to either make comments on your application or discuss their comments with you outside of the system.
Your supervisor will need to electronically send the application back to you for editing through the options listed in the action tab.
Once your supervisor electronically endorses your application it will available for the Faculty to review.
You must provide a signed copy for the Faculty before they can electronically endorse your application.

If you would like any further information please see our instructions or contact the Ethics Secretariat by email or on (02) 9514 9772.
You can also watch videos on how to submit this form or download detailed instructions about the form and its features.

Faculty Research Office only

Faculty Research Office check

Faculty Research Office only
Has this application been printed, signed and a hardcopy received by the Faculty Research Office?

○ Yes

○ No

This question is not answered.

Comments/Notes:

This question is not answered.

Dear Anantdeep

I am now able to formally confirm that your DSP stage 1 assessment has been assessed and the result is satisfactory.

GRS has been informed.

Your progression to stage 2 is confirmed.

For your information I have attached the assessors reports.

If you need more information, please contact science.maps@uts.edu.au

Congratulations.

Our apologies that this has taken so long to finalise.

Kind regards

Sarah

Sarah King | Research Officer
School of Mathematical and Physical Sciences
Faculty of Science

UNIVERSITY OF TECHNOLOGY, SYDNEY
City Campus – Level 5, Building 4 (CB04.05.428.03)
PO Box 123 Broadway NSW 2007
Street Address: 638 Jones Street, Ultimo NSW 2007
T: +61 2 9514 2490 | F: +61 2 9514 2260

The Ethics Committee operates in accordance with the National Statement on Ethical Conduct in Research Involving Humans, 1999

Charles Connibere Building
The Royal Melbourne Hospital
Flemington Road
Parkville Victoria 3052
Telephone 61 3 9342 8155
Facsimile 61 3 9342 8813
Website www.mh.org.au
ABN 73 802 706 972

MELBOURNE HEALTH

Research Directorate - Human Research Ethics Committee Approval Form

Telephone: 9342 8530 Facsimile: 9342 8548

This is to certify that

CREC Project No: 2003.009 **Approval date: 19-Apr-2003**

Expiry date: 19th April 2006

Project Title Gluten Immunity in Coeliac Disease

Principal Investigator: Dr. Robert Anderson

Protocol No: N/A

Anticipated duration of Study: from 01/03/03 to 01/03/05

Participant Information and Consent Form: Version 2, dated 11th March, 2003

Investigator Brochure:

Other enclosures: (please describe eg advertisement etc.)

Conducted at: Royal Melbourne Hospital has been approved.

It is now your responsibility to ensure that all people conducting this research project are made aware of which documents have been approved.

This approval is subject to ongoing, current and valid insurance coverage throughout the duration of the conduct of the study.

You are required to notify the Secretary of the Human Research Ethics Committee of

- Any change in the protocol and the reason for that change together with an indication of ethical implications (if any) by submitting an amendment to the study.
- Serious adverse effects on subjects and the action taken to manage them, including amended Plain Language Statement and Consent Form where appropriate.
- Any unforseen events.
- Your inability to continue as Principal Investigator, or any other change in research personnel involved in the study
- A delay of more than 12 months in the commencement of the project.
- The actual date of commencement of the study.

You are required to submit to the Human Research Ethics Committee

- An Annual Report every twelve months for the duration of the project.
- A detailed Final Report at the conclusion of the project.

The Human Research Ethics Committee may conduct an audit at any time.

An extension of the project beyond the stated conclusion date should be sought from the Human Research Ethics Committee.

Signed: .....

Dr. Angela Watt
Secretary – Human Research Ethics Committee

The Royal Melbourne Hospital
Parkville Victoria 3050
Telephone 61 3 9342 8530
Facsimile 61 3 9342 8548
Email: research@mh.org.au
Website: http://research.mh.org.au
ABN 73 802 706 972

MELBOURNE HEALTH

OFFICE FOR RESEARCH

APPROVAL OF AMENDMENT

18 July 2016

Dear Dr. Jason Tye-Din,

Local Project Number: 2003.009

Research Title: Gluten Immunity in Coeliac Disease

Type of review:
HREC and Governance Review

I am pleased to advise that the amendment to the above project has been reviewed and approved by the Melbourne Health HREC (ethical approval). This approval applies to all sites for which the Melbourne Health HREC has issued ethical approval. The amendment has also been approved to be conducted at Melbourne Health (governance approval).

Amendment Approval Date: 14 July 2016

Approved Documents:

- Protocol, Version 9.4, dated 04 July 2016

Please refer to the Melbourne Health Office for Research website to access guidelines and other information and news concerning research at:
http://www.mh.org.au/www/342/1001127/displayarticle/1001352.html

Please Note: Template forms for reporting Amendments, Adverse Events, Annual Report/Final Reports, etc. can be accessed from:: www.health.vic.gov.au/cchre.

For any queries about this matter, please contact Ms Jessica Turner on 9342 8530 or via email on: Jessica.Turner@mh.org.au

Yours sincerely,

Ms. Jessica Turner
Manager - Human Research Ethics Committee
Ph: 03 9342 8530