Project | Create Sub Form | 6 Reviewer Comments

View as PDF

HC230343 (MM) The response of the eye to different ocular allergy eyedrops. 4660

Note: There is a newer version of the project. *(Please contact the project owner to update this form).*

Project Tree

- HC230343 (MM) The response of the eye to different ocular allergy eyedrops.
  - Human Ethics Application

Action Required on Form	Status	Review Reference	Application Type	Date Modified
No	Approved	iRECS4660	Legacy more than low risk modification	09/10/2023 00:16

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Show Inactive Sections

Human Ethics Application

Section	Questions
Before you start	Before you start
New Application / Modification Request	New Application / Modification Request
Submission Type	Submission Type: Minimising the Duplication of Ethical Review
Project Details	Project Details
Research Personnel	Research Personnel

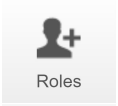
Human Ethics Application

Before you start

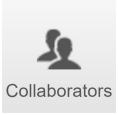
Note: Below is some helpful guidance completing this form. Please note that the session will time out after 30 minutes of inactivity. It is advised that you regularly save to ensure no content is lost. The form accepts plain text only (no special formatting). You can upload attachments to the form if special formatting is required (e.g. charts, illustrations etc.)

To save your form progress select the **'Save'** button. iRECS sessions will expire after 30 minutes of inactivity.
Note (i) iRECS will only auto-save form content upon clicking on the "Previous" and/or "Next" buttons and (ii) the 'View As Table' feature in the main form will only become activated (i.e. populate with specified data) after the form content is saved.

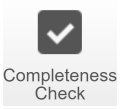
To return to the form navigation screen select the **'Navigate'** button. Here you can see all information associated with the project including the history of submissions, correspond with RECS secretary and create sub forms.



To share access to this form select the **'Roles'** button or select **'Assign Role'** at any personnel questions. You can choose what permissions (read, write, or submit) each user receives.

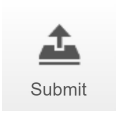


To view which users currently have access to this form select the **'Collaborators'** button. This will show what level of access each user has to your form.



To perform a completeness check (checks mandatory questions are answered), select the **'Completeness Check'** button.

To view your form as a PDF, select the **'View as PDF'** button.



To submit your completed form, select the **'Submit'** button.

New Application / Modification Request

*If this is the first time you are completing this form or if it has not been reviewed and approved please select **'New Application'**. To modify the application after approval select **'Modification'**and provide a brief summary of the requested modifications. **'Legacy Project Modification'** should be used for modification of pre-iRECS approved project/application.*

○ New Application

Select this option if you are lodging a new application OR if you are revising an unapproved application.

○ Modification

Select this option if you are modifying OR revising an approved application.

◉ Legacy Project Modification (only applicable for pre-iRECS approved projects)

Select this option if you are modifying or revising a project that is approved prior to iRECS rollout.

For migrated projects (pre-iRECS approved), please keep the Legacy Project Modification option checked. Changing this response will lead to loss of migrated legacy data.

Submission Type

For migrated projects (pre-iRECS approved), DO NOT modify the selected response for this question, as it will lead to loss of migrated legacy data.

Indicate the submission type:

☑ Human Research Ethics Submission

Human research involves observing and collecting data/biospecimens from or about human subjects to answer a specific research aim or research questions. The following are examples of research activities:

- Surveys, interviews or focus groups.
- Psychological, physiological, or medical testing or treatment.
- Observation of people.
- Obtaining access to or extracting information about a person from documents, medical records, databases, social media, websites, pathology services, data, or tissue banks.
- Administration of medical, psychological, or physiological intervention.
- The collection and use of a person's biological material (body organs, tissues, fluids, or exhaled breath).

☐ External Ethics Submission

External ethics approval is defined as ethical approval established with a

- NHMRC-registered Australian HREC has been established for a human research project.
- An overseas international review board where:
  - Participants within Australia will not be recruited.
  - UNSW will not be responsible for the conduct of the research at an Australian site.
  - A UNSW researcher, staff member or student will not be responsible for fieldwork, recruitment, or data collection overseas

☐ Coursework Submission

Coursework submissions facilitate ethical review of the risk assessment process for groups of student projects conducted as part of a research course requirement. Student projects covered by this process involve people participating in research interviews, surveys, questionnaires, or observations for a research purpose. Therefore, the relevant course convenor can only submit the coursework applications.

☐ Notification of Publicly Available Dataset Submission

The notification process is only to be used to register human research projects involving the exclusive use of secondary data extracted from one of the pre-determined publicly available datasets, which contains only non-identifiable data.

Project Details

Project Title

HC230343 (MM) The response of the eye to different ocular allergy eyedrops.

Is there Research Grant Funding associated with this Project?

This excludes HDR scholarships, stipend and/or payments.

○ Yes
◉ No

How will the conduct of the research be supported?

◉ UNSW Faculty or School Support
○ Other

Research Personnel

Tip:

- Enter staff zID or name into the 'Search User' field and press 'Tab' to auto-populate researcher/staff details into the corresponding personnel fields.
- Once the personnel details are populated, click on the 'Assign Role' button to assign the researcher/staff with the desired access permission for the proposal. Doing so enables the assigned researcher/staff to read, write(edit) and/or submit the proposal depending on the level of access you provide them. Note that the project/form owner will automatically be assigned as a collaborator (read, write & submit) for the project, so they can bypass the 'Assign Role' step.
- For external researchers/users, please reach out to the Human Ethics Team to have their external profile established on iRECS, this will enable them to access iRECS and be listed as a collaborator against the project.

Coordinating Chief Investigator

- The Chief or Coordinating Investigator must be a staff member of UNSW or one of its affiliated centres or institutes.
- A student cannot be listed as the Chief Investigator. However, the supervisor must be the chief investigator if a UNSW student undertakes the project.
- An external entities agreement must be in place, and a fee for review paid before research from external organisations will be accepted for review. Please contact the Human Ethics Team to establish this agreement.

User Profile Search

In the "Search User" field below enter the Coordinating Chief Investigator ZID, or first name followed by the surname and user profile will populate. Next, select the user by clicking on profile that populates and then press 'Tab' to auto-populate the relevant researcher/staff details into the corresponding personnel fields. If the user profile does not appear, you can complete the details manually in the fields below.

Title	Sci
First Name	Fiona
Surname	Stapleton
Faculty / Division / Institution	Medicine & Health
School / Centre / Unit	School of Optometry
UNSW Appointment Type	Other
Describe:	Data not available on legacy system, please update as necessary
Email	[redacted]
Contact Number	[redacted]
zID	[redacted]

Specify this person's responsibilities for this project and explain how they are experienced (qualifications and training) to complete these duties.

Supervision, direction and oversight of the project, interpretation and dissemination of results. The chief investigator is an optometrist and Scientia Professors at the School of Optometry and Vision Science. (SOVS).

Does your project involve any of the following personnel

- [x] Co-investigators/Research personnel
- [ ] Students

Co-Investigator / Research Personnel

User Profile Search

In the "Search User" field below enter the relevant personnel's ZID, or first name followed by the surname and user profile will populate. Next, select the user by clicking on profile that populates and then press 'Tab' to auto-populate the relevant researcher/staff details into the corresponding personnel fields. If the user profile does not appear, you can complete the details manually in the fields below.

Title	Mr
First Name	Ali
Surname	Alghamdi
Faculty / Division / Institution	Medicine & Health
School / Centre / Unit	School of Optometry (Summ)
UNSW Appointment Type	Other
Describe:	Data not available on legacy system, please update as necessary
Email	[redacted]
Contact Number	[redacted]
zID	[redacted]

Specify this person's responsibilities for this project and explain how they are experienced (qualifications and training) to complete these duties.

Data collection, measurements and analysis. The PhD student is an experienced optometrist and is in its 2nd year of PhD. The student has previous experience with data collection method and studies of similar nature.

Co-Investigator / Research Personnel

User Profile Search

In the "Search User" field below enter the relevant personnel's ZID, or first name followed by the surname and user profile will populate. Next, select the user by clicking on profile that populates and then press 'Tab' to auto-populate the relevant researcher/staff details into the corresponding personnel fields. If the user profile does not appear, you can complete the details manually in the fields below.

Title	Apro
First Name	Blanka
Surname	Golebiowski

Faculty / Division / Institution	Medicine & Health
School / Centre / Unit	School of Optometry
UNSW Appointment Type	Other
Describe:	Data not available on legacy system, please update as necessary
Email	[redacted]
Contact Number	[redacted]
zID	[redacted]

Specify this person's responsibilities for this project and explain how they are experienced (qualifications and training) to complete these duties.

Supervision, direction and oversight of the project, interpretation and dissemination of results. The co-Investigator is is an optometrist and Associate Professor in the School of Optometry and Vision Science (SOVS).

Co-Investigator / Research Personnel

User Profile Search

In the "Search User" field below enter the relevant personnel's ZID, or first name followed by the surname and user profile will populate. Next, select the user by clicking on profile that populates and then press 'Tab' to auto-populate the relevant researcher/staff details into the corresponding personnel fields. If the user profile does not appear, you can complete the details manually in the fields below.

Title	Prof
First Name	Isabelle
Surname	Jalbert
Faculty / Division / Institution	Medicine & Health
School / Centre / Unit	School of Optometry
UNSW Appointment Type	Other
Describe:	Data not available on legacy system, please update as necessary
Email	[redacted]
Contact Number	[redacted]
zID	[redacted]

Specify this person's responsibilities for this project and explain how they are experienced (qualifications and training) to complete these duties.

Supervision, direction and oversight of the project, interpretation and dissemination of results. The co-Investigator is is an optometrist and Professor in the School of Optometry and Vision Science (SOVS).

Legacy Modification

Legacy Project Number

HC230343

Legacy Project Title

The response of the eye to different ocular allergy eyedrops.

Legacy Risk Level

More than Low Risk

Legacy Clinical Trials

- (•) Yes
- ( ) No

Legacy Approving HREC Name

HREC Committee C

Legacy Modification Summary

The exclusion criteria have been updated. The following criteria have been:
• Severe asthma.
• Severe eczema.
• Past anaphylactic episode.
These criteria were added to ensure more safety for the study participants. This section has been updated in all relavent documents.

Legacy Modification Summary

Improve the consistency of the intervention concentration percentage (Ketotifen 0.025%) in the clinical protocol document (see section 11).

Legacy Modification Summary

The record form has been updated. A recording field has been added for the measurement of the Non-Invasive Tear Break Up Time (NITBUT). The biomicroscopy table has been reformatted.

Legacy Modification Summary

The Allergy Symptoms Questionnaire has been updated. Blurriness and Tiredness have been added to the Allergy Symptoms Questionnaire, and the table has been reformatted. General wording improvement.

Documents

Type	Document Name	File Name	Version Date	Version	Size
PROTOCOL	Project Description_v3_FS_HC230343_04102023_Clean Version	Project Description_v3_FS_HC230343_04102023_Clean Version.docx	04/10/2023	3	177.3 KB
PROTOCOL	Clinical Trial Protocol [Investigational Medical Product]_v3_FS_HC230343_04102023_Clean Version	Clinical Trial Protocol [Investigational Medical Product]_v3_FS_HC230343_04102023_Clean Version.docx	04/10/2023	3	317.5 KB
PROTOCOL	Record form_v3_FS_HC230343_04102023_Clean Version	Record form_v3_FS_HC230343_04102023_Clean Version.docx	04/10/2023	3	218.1 KB
PROTOCOL	Participation Information Statement and Consent Form_v3_FS_HC230343_04102023_Clean Version	Participation Information Statement and Consent Form_v3_FS_HC230343_04102023_Clean Version.docx	04/10/2023	3	104.9 KB
PROTOCOL	Recruitment Letter_v3_FS_HC230343_04102023_Clean Version	Recruitment Letter_v3_FS_HC230343_04102023_Clean Version.docx	04/10/2023	3	99.3 KB
PROTOCOL	Study Advertisement_v3_FS_HC230343_04102023_Clean Version	Study Advertisement_v3_FS_HC230343_04102023_Clean Version.docx	04/10/2023	3	2.5 MB
PROTOCOL	Combined Questionnaires_v3_FS_HC230343_04102023_Clean Version	Combined Questionnaires_v3_FS_HC230343_04102023_Clean Version.pdf	04/10/2023	3	644.9 KB

Track Changes Legacy Project Document Upload

Documents

Type	Document Name	File Name	Version Date	Version	Size
PROTOCOL (TRACKED)	Project Description_v3_FS_HC230343_04102023_Tracked Version	Project Description_v3_FS_HC230343_04102023_Tracked Version.docx	04/10/2023	3	175.2 KB
PROTOCOL (TRACKED)	Clinical Trial Protocol [Investigational Medical Product]_v3_FS_HC230343_04102023_Tracked Version	Clinical Trial Protocol [Investigational Medical Product]_v3_FS_HC230343_04102023_Tracked Version.docx	04/10/2023	3	322.1 KB
PROTOCOL (TRACKED)	Record form_v3_FS_HC230343_04102023_Tracked Version	Record form_v3_FS_HC230343_04102023_Tracked Version.docx	04/10/2023	3	219.2 KB
PROTOCOL (TRACKED)	Participation Information Statement and Consent Form_v3_FS_HC230343_04102023_Tracked Version	Participation Information Statement and Consent Form_v3_FS_HC230343_04102023_Tracked Version.docx	04/10/2023	3	102.3 KB
PROTOCOL (TRACKED)	Recruitment Letter_v3_FS_HC230343_04102023_Tracked Version	Recruitment Letter_v3_FS_HC230343_04102023_Tracked Version.docx	04/10/2023	3	100.3 KB
PROTOCOL (TRACKED)	Study Advertisement_v3_FS_HC230343_04102023_Tracked Version	Study Advertisement_v3_FS_HC230343_04102023_Tracked Version.docx	04/10/2023	3	2.5 MB
PROTOCOL (TRACKED)	Combined Questionnaires_v3_FS_HC230343_04102023_Tracked Version	Combined Questionnaires_v3_FS_HC230343_04102023_Tracked Version.pdf	04/10/2023	3	635.8 KB

Participants and Area of Research

Indicate the type of research that will be conducted:

- *If more than one option applies make multiple selections.*
- *Note that this question is a requirement by NHMRC for their reporting purposes.*

- ☐ Public Health Research
- ☐ Qualitative Research
- ☐ Quantitative Research
- ☐ Social Policy Research
- ☑ Clinical Research (other than Clinical Trials)
- ☐ Clinical Trials Research
- ☐ Education Research
- ☐ Other

Indicate the target population for this research

- *If more than one option applies make multiple selections.*
- *Note that this question is a requirement by NHMRC for their reporting purposes.*

- ☐ Aboriginal and/or Torres Strait Islander People
- ☐ Ageing Populations
- ☐ Children and Young People (under age of 18)
- ☐ General Public
- ☐ People Highly Dependent on Medical Care
- ☐ People in other countries
- ☐ People who may be involved in illegal behaviour
- ☐ People with a cognitive impairment, physical impairment, an intellectual disability, or a mental illness
- ☐ Populations belonging to specific industry sectors
- ☐ Prison Populations
- ☐ School Students
- ☐ University Students
- ☐ SONA Participants
- ☑ Other

Other:

Adult participants with eye allergies

Committee / Panel

The responses provided in the risk assessment indicate that your research is more than low-risk research which will be reviewed by one of the UNSW Human Research Ethics Committee (HREC). Check the box below to proceed:

- ☑ Accept

Research Details

Does this research involve the collection of data from participants located within Australia?

- ◉ Yes
- ○ No

Will this data be collected in person or online?

- ☑ In person
- ☑ Online
- ☐ Access via existing records
- ☐ Other

In Person Collection

Select the Australian states or territories where data collection will occur:

☐ ACT ☑ NSW ☐ NT ☐ QLD ☐ SA ☐ TAS ☐ VIC ☐ WA

Data will be collected at a research data collection site?

◉ Yes
○ No

Site Details

Specify the the name of the organisation or research site where this data will be collected.

If the sites are to be determined before recruitment and data collection commences, specify that the site will be determined before recruitment and data collection commences and a modification request will be submitted via iRECS to establish approval for this additional site.

School of Optometry and Vision Science

Attach the letter of support from the specified site

Online Collection

Select the Australian states or territories where data collection will occur:

Note: If you are unsure where your online data collection will occur, choose the 'Other' response option and provide information in the free text field.

☐ ACT ☑ NSW ☐ NT ☐ QLD ☐ SA ☐ TAS ☐ VIC ☐ WA ☐ Other

Research Details

Does this research involve the collection of data from participants located in another country?

○ Yes
◉ No

Clinical Trial Details

Indicate the type of sponsor for the trial.

- (•) Investigator-Initiated

  Trials developed and managed by clinicians and researchers working part of an institution or university. The institution that is responsible for the clinicians or researchers will be responsible as a trial sponsor.

- ( ) Collaborative Research Group

  A group of researchers and/or clinicians from different organisations that collaborate together to facilitate the establishment and management of a trial. The organisations responsible for the researchers will be responsible as the clinical trial sponsor.

- ( ) Contract Research Organisation

  A contracted organisation that provides clinical trial support for pharmaceutical, biotechnology, or medical device industries. The organisation completes the sponsor responsibilities on behalf of another organisation.

- ( ) Commercial Sponsor

  An organisation that initiates, organises, and supports clinical trials and provides medico-legal responsibility associated with the conduct of the trial. Therefore would be considered the sponsor of the study.

Indicate the type of clinical trial:

- [ ] Clinical trial involving a health intervention.
- [x] Clinical trial involving a medical product.
- [ ] Clinical trial involving a medical device.
- [ ] Clinical trial involving a surgical intervention.
- [ ] Other

Indicate the phase of the clinical trial:

- [ ] Phase I
- [ ] Phase II
- [x] Phase III
- [ ] Phase IV
- [ ] Other clinical trials

Clinical Trial Protocol

Enter the current version number and date of the clinical trial protocol

04 October 2023 – version 3

Has the clinical trial been registered on a publicly accessible register complying with international standards?

- ( ) Yes
- (•) No

You must register and advise the details of the registration number before recruitment and data collection commences. Confirm that this will occur.

- [x] Confirm

Will/has the trial be notified via the Therapeutic Goods Administration Clinical Trial Notification process?

- (•) Yes
- ( ) No

Indicate the status of the CTN submission.

- [ ] Pending submission
- [x] Submitted

Enter the CTN reference number for this submission

CT-2023-CTN-04066-1

Specify the name of the trial sponsor.

UNSW

Sponsor responsibilities for this trial must be confirmed by the UNSW Sponsors Delegate before recruitment and data collection commences. Have these responsibilities been confirmed?

Sponsor Responsibilities

UNSW's role as clinical trial sponsor is not automatically confirmed. UNSW researchers and staff members must obtain written confirmation from the UNSW Sponsors Delegate before recruitment and data collection for a clinical trial commences. UNSW can assume the role of trial sponsor for clinical trials conducted within Australia that meet UNSWs criteria for trial sponsorship. A list of the criteria is specified on the Sponsor Related Responsibilities webpage.

- (•) Yes
- ( ) No

Attach a copy of correspondence confirming the sponsor responsibilities for the clinical trial.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Supporting documents	Sponsor Responsibilities Letter Confirmation_HC230343_23082023	Sponsor Responsibilities Letter Confirmation_HC230343_23082023.pdf	23/08/2023	1	178.4 KB

The UNSW clinical trial protocol template must be used for all clinical trials that UNSW Sponsors. Has the clinical trial protocol been developed using the UNSW protocol template?

- Clinical Trial Protocol Template [Medical Device]
- Clinical Trial Protocol Template [Medical Product]
- Clinical Trial Protocol Template [Health Intervention]

- (•) Yes
- ( ) No

Please attach a completed copy of your UNSW Clinical Trial Protocol.

UNSW Insurance cover must be confirmed for all clinical trials that UNSW Sponsors. Has insurance cover for the clinical trial been confirmed?

- (•) Yes
- ( ) No

Attach a copy of the completed clinical trials insurance spreadsheet.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Supporting documents	UNSW_Clinical Trials Insurance Certificate_COC-2022-2023_HC230343_26072023	UNSW_Clinical Trials Insurance Certificate_COC-2022-2023_HC230343_26072023.pdf	26/07/2023	1	153.4 KB

Attach a copy of the submission email to financehelp@unsw.edu.au.

Provide details of each clinical trial site where the trial will be conducted.

Site Name

School of Optometry and Vision Science

Institution responsible for the clinical trial site

UNSW

Principle Investigator Responsible for the clinical trial site

Fiona Stapleton

Status of CTRA

Not required

Access to existing collections of data or biospecimens for secondary research

Does the research involve access to existing collections of data or biospecimens?

- ( ) Yes
- (•) No

Attachments

Upload relevant letters of support and copies of all documents that will be administered to the research participants or will be used to collect participant data. If you have uploaded these while completing the application form you do not need to upload them again.

Examples of the documents to be provided are as follows:

- Recruitment materials, including study advertisements, email, social media, or letters of invitation.
- Participant information statement and consent forms.
- Data collection tools, including survey tools, interview guides, and focus group/observation guides.
- Letters of support from participating organisations.

If your research involves the administration of ionising radiation, please attached a copy of the Radiation Safety Committee Approval and/or Radiation Safety Officer Approval.

Optional: Upload a flow chart or table of events to be used in this human research.

Declaration

If you have created this application on behalf of a Chief Investigator (CI), you must transfer this project to the CI to complete the final (Declaration and Submission) steps. Instructions for transferring a project can be found in the help section of iRECS.

As the submitting investigator of the research, I confirm that:

- The information provided in the submission is accurate, correct, and complete.
- I will ensure that the investigators and study personnel conduct the research following the National Statement on Ethical Conduct in Human Research (updated 2018) requirements.
- I will ensure that the investigators and study personnel will not commence recruitment, data collection or access data from existing collections (if applicable) without written confirmation of human ethics approval.
- Qualified research personnel will conduct all research procedures for both training and experience.
- I will ensure that all research personnel follow the approved protocol, procedures, terms, and conditions specified by the HREC/HREAP when conducting this human research once approved.
- I will ensure that approval will be sought for all modifications made to the research before implementing them in the conduct of the research.
- I will ensure that any conditions of approval will be met, and any requisite approvals, permits or regulatory processes relevant to the research will be obtained before recruitment, and data collection commences.
- I have read and understood the applicable UNSW Workplace Health and Safety policies. Therefore, we will undertake all appropriate training in Workplace Health and Safety as dictated by UNSW policies.
- The human research proposal has been provided to the head of the school for approval or their information before submission.

☑ Accept

Submission