

REGGS Ethics & Governance: How-To Guides

Project Registration

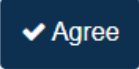
How to Register a Project in REGGS


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Step 1


- Before you can complete and submit an SSA or HREA, **you must register your project**, using the steps below.
- Log into REGGS.

Step 2

- A “Licence agreement” notice will appear on your screen.
- Click 
- This will log you into your account.



Welcome to REGGS Ethics & Governance


 Log in as a Ramsay user


OR

User name*

Password*

[Show password](#)


 Log in



Licence agreement

This is a restricted system. Use of this system is monitored at all times and requires explicit permission from the system administrator. If you do not have this permission, you are violating the regulations of this system and can and will be prosecuted to the full extent of the law.

By continuing into this system, you are acknowledging that you are aware of and agree to these terms.

[Decline](#) 

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Step 3

- On your home page, select Projects from the banner on the top of the screen or click on + New Form – this will take you to the Projects page.

Step 4

- On the Right-Hand Side (RHS), select the button + New Project and when the New Project box pops up into the middle of the screen, select **Project Registration**.

The screenshot shows the REGGS Ethics & Governance interface. The top navigation bar includes 'Applications', 'Decisions', 'Reviews', 'Meetings', 'Projects', and 'Dashboards'. The 'Projects' icon is highlighted with a red box. A red arrow points from the 'Projects' icon in the navigation bar to the 'Project Registration' option in the 'Create a form' section. The 'Create a form' section has a red box around the '+ New form' button and the 'Project Registration' option.

Research Applicants
This home page will list below the 5 most recently registered projects you have access to as the application owner or permitted user. Click on the project link (e.g. 2021/PID/0001) to view project details, including associated ethics and governance applications.

To register a new project, use the "New form" button below or click on the "Projects" icon above.

To continue an in-progress registration or view/manage other registered projects not listed below, please click on the "Projects" icon in the menu bar at the top of this page or use the "View all" button in the bottom right hand corner of the "Top 5 Projects" section below.

Other users - Executives/Delegates, HREC Members, External Reviewers, etc.
Depending on your role, you may have additional icons in the bar above such as 'Decision', 'Meetings' and/or 'Review'. If you have received a notification that you have an activity to view in those areas, select the related icon to access the area you require.

Create an application

+ New form	Site
+ New form	Ethics
+ New form	Authorised Prescribe Scheme

Create a form

+ New form	Invoice Details Form
+ New form	Project Registration

Top 5 projects

2022/PID/0847 A Phase 3, Multi-Arm , Multi-Stage Covari... 2019/ETH/1921	Registered	26/08/2019
2022/PID/0064 Leslie's Test of the full system	Registered	09/05/2022
2024/APS/0009 APS Leslie Testing	Approved	29/08/2024
2022/PID/0059 x	Completed	04/02/2022
2022/PID/1669 One more test	Registered	13/05/2022

[View all](#)

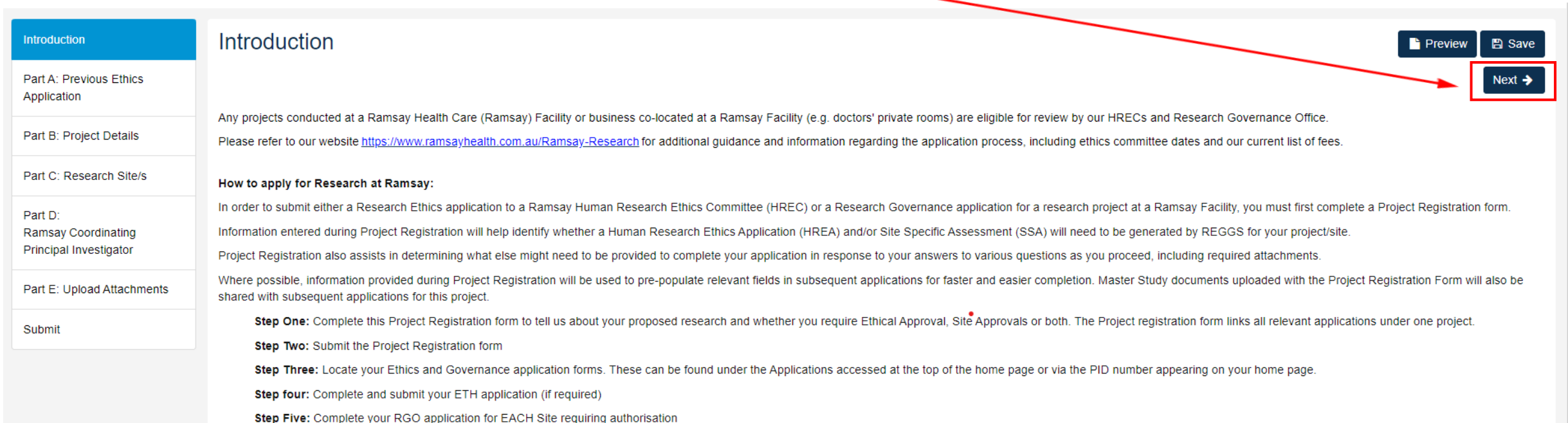
Top 5 milestones due

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Step 5

- Read carefully over the Introduction page and then select 'Next' on the RHS of the page.

A screenshot of the REGGS 'Introduction' page. On the left is a sidebar with a blue header 'Introduction' and a list of sections: 'Part A: Previous Ethics Application', 'Part B: Project Details', 'Part C: Research Site/s', 'Part D: Ramsay Coordinating Principal Investigator', 'Part E: Upload Attachments', and 'Submit'. The main content area is titled 'Introduction' and contains text about project eligibility, a link to the Ramsay Research website, and a 'How to apply for Research at Ramsay' section with five numbered steps. In the top right corner of the main content area, there are three buttons: 'Preview', 'Save', and 'Next →'. A red arrow originates from the instruction in Step 5 and points directly to the 'Next →' button, which is also highlighted with a red rectangular box.

Introduction

Part A: Previous Ethics Application

Part B: Project Details

Part C: Research Site/s

Part D: Ramsay Coordinating Principal Investigator

Part E: Upload Attachments

Submit

Introduction

Any projects conducted at a Ramsay Health Care (Ramsay) Facility or business co-located at a Ramsay Facility (e.g. doctors' private rooms) are eligible for review by our HRECs and Research Governance Office. Please refer to our website <https://www.ramsayhealth.com.au/Ramsay-Research> for additional guidance and information regarding the application process, including ethics committee dates and our current list of fees.

How to apply for Research at Ramsay:

In order to submit either a Research Ethics application to a Ramsay Human Research Ethics Committee (HREC) or a Research Governance application for a research project at a Ramsay Facility, you must first complete a Project Registration form. Information entered during Project Registration will help identify whether a Human Research Ethics Application (HREA) and/or Site Specific Assessment (SSA) will need to be generated by REGGS for your project/site. Project Registration also assists in determining what else might need to be provided to complete your application in response to your answers to various questions as you proceed, including required attachments. Where possible, information provided during Project Registration will be used to pre-populate relevant fields in subsequent applications for faster and easier completion. Master Study documents uploaded with the Project Registration Form will also be shared with subsequent applications for this project.

Step One: Complete this Project Registration form to tell us about your proposed research and whether you require Ethical Approval, Site Approvals or both. The Project registration form links all relevant applications under one project.

Step Two: Submit the Project Registration form

Step Three: Locate your Ethics and Governance application forms. These can be found under the Applications accessed at the top of the home page or via the PID number appearing on your home page.

Step four: Complete and submit your ETH application (if required)

Step Five: Complete your RGO application for EACH Site requiring authorisation

Preview Save

Next →

Note: You cannot edit a Project Registration after it has been submitted.


How to Register a Project in REGGS


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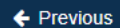
Step 6

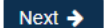
- Answer all questions in Parts A through to D – **Part A – Previous Ethics Application** – Whether the project is covered under Ramsay's HREC A or WA/SA or an external, NHMRC Certified Board; e.g. Bellberry, St Vincent's, Monash etc.

Part A: Previous Ethics Application

 Preview

 Save

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A1 Will the Ramsay Health Care sites participating in this project be covered under any existing or planned ethics submission to an NHMRC Certified HREC external to Ramsay Health Care? ⓘ *

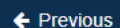
☒ Yes ☐ No

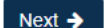
If you are intending to submit your project to a Ramsay HREC for ethical review, answer "No" for Question A1.

If you have existing HREC approval for this project (via a Ramsay HREC or an external HREC), or you are intending to apply to an external HREC, please answer "Yes" for Question A1. The existing HREC approval must list the relevant Ramsay sites.

If your external approving HREC will not agree to cover participating Ramsay sites, or does not appear in the HREC dropdown list below, you will be required to submit your project to a Ramsay HREC for review.

Please contact ResearchGovernance@ramsayhealth.com.au before submitting your form if you are unsure how to answer this question or have any questions.

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Next 

Yes: Only click yes if your site is included on the ethics approval letter from an external HREC as either the lead or supporting site.

No: Click 'no' if there is no existing external approval and you are not seeking ethics approval from an external HREC such as Bellberry, or if the external approval is from a body (e.g. from a public health HREC) that will not include your Ramsay site. In both these cases you will need to submit an ethics application to a Ramsay HREC.



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Step 7

- **Part B – Project Details** - Answer every question on this page, ensuring you provide a lay-person summary of the activities to be conducted at the Ramsay Health Care Facility.

Part B: Project Details

[Preview](#)[Save](#)[← Previous](#)[Next →](#)

B1 Project Title ⓘ *

ABC-1234 versus DEF-5678 in combination with polatuzumab-vedotin, as primary treatment for patients with diffuse large B-cell lymphoma, an open label randomized Nordic Lymphoma Group phase III trial.

B2 Lay person summary of the Research Project (including the Activities to be conducted at the Ramsay Health Care Facility) *

This trial will test the efficacy of the combination of ABC-1234, compared to DEF-5678, the standard of care treatment, determined by how long participants remain free of lymphoma and if treatments differ in side effects. This combination of reduced dose is not an approved treatment by the TGA in Australia, therefore, ABC-1234 is the experimental treatment. This trial will recruit participants 80 years and older or frail adult participants 75 years and older with laboratory confirmed Lymphoma that has not yet been treated. Patients will be admitted to the Day Cancer Unit, both the experimental arm and the standard of care treatments will be administered via intravenous infusion over a period of several hours, every 21 days for a total of 6 cycles. All infusions and safety monitoring will be conducted by Ramsay Private Hospital.

B3 Category of research ⓘ *

- ☐ Anaesthesiology
- ☐ Cardiorespiratory Medicine and Haematology
- ☐ Clinical Quality Registry
- ☐ Clinical Sciences - 1103
- ☐ Device (treatment, prevention, screening & diagnostic)
- ☐ Endocrinology
- ☐ Gastroenterology
- ☒ Hepatology
- ☐ Human Movement and Sports Science - 1106
- ☐ ICU

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Step 8

- **Part C - Research Sites** – Under **Ramsay Health Sites**, select + **Add Site** and **Project Centre** as **Ramsay Health Care** nominate the **Ramsay Project Site** and the relevant **Principal Investigator** for each site. A Site-Specific Assessment (SSA) will be generated for each site nominated.

List all Ramsay Facilities under the Ramsay Health Sites tab.

Please click on the "Other Sites" tab to add Doctors' Private Rooms and/or external organisations co-located within Ramsay facilities which are eligible to apply for Ramsay Health Care HREC oversight.

Ramsay Health Sites

Nominate the project site/s within Ramsay Health and a Principal Investigator for each site

Please nominate the Ramsay project site(s) and the relevant Principal Investigator for each site. A Site Specific Assessment (SSA) will be generated for each site nominated.

A Principal Investigator (PI) is the person responsible for the conduct of research at that site. The Ramsay Coordinating Principal Investigator (CPI) may also be the PI .

The PI for each site must be either an Accredited Practitioner, an Accredited Allied Health Practitioner or an Employee at the site in which they are conducting research.

Each Site PI is responsible for submitting the SSA for their own site.

Please note the PI is the only person who has the authority to submit the SSA in REGGS. Incorrectly listing the PI will cause the application to be ineligible and will result in your application being returned to you for correction.

Project Centre *

Ramsay Health Care

Project Site *

Border Cancer Hospital

Principal Investigator email (REGGS username) *

silkl@ramsayhealth.com.au

Principal Investigator name

Dr Leslie Silk

+ Add Site



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Step 9

- **Part D – Ramsay Coordinating Principal Investigator** – Please answer No for ‘Are you the Ramsay Coordinating Principal Investigator for this project?’ then type in the email address of the Principal Investigator (which is also their REGGS username).

Part D: Ramsay Coordinating Principal Investigator

[Preview](#)[Save](#)[< Previous](#)[Next >](#)

In the context of REGGS, the **Ramsay** Coordinating Principal Investigator (CPI) holds overall responsibility for the study **across/within Ramsay project sites only**.

Note: The Ramsay CPI may not necessarily be the overall Coordinating principal investigator across all study sites.

The **Ramsay CPI** must be either an Accredited Practitioner, an Accredited Allied Health Practitioner or an Employee at one or more of the Ramsay research sites for this study.

If this project requires Ramsay HREC review, the Ramsay CPI will be responsible for submitting the HREA on behalf of all Ramsay sites. If the Ramsay CPI is also nominated as a PI for one or more sites, they will also be required to submit the SSA for those sites.

For research conducted at a single Ramsay site which has external ethical oversight, please list the Site PI as the Ramsay CPI below.

Please note that **the Ramsay CPI must have a REGGS user profile before you will be able to complete this form**. As you enter the CPI's email address, REGGS will search for a match with a registered user.

If no match is found, please leave the CPI email blank and select 'Invite to Register'.

[Invite to Register](#)

Are you the Ramsay Coordinating Principal Investigator for this project?*

The Ramsay CPI is the person that holds overall responsibility for the study within Ramsay. They are the only person who has the authority to submit the Ramsay Ethics application (if relevant).

An incorrect response here WILL cause the application to be ineligible and will result in your application being returned to you for correction.


☐ Yes ☒ No

CPI email (REGGS user name)*

silk@ramsayhealth.com.au

CPI Name

Dr Leslie Silk

ORCID 

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Step 10

➤ **Part E – Upload Attachments** – Please upload a copy of the Study Protocol or Project Description and any other **Master Documentation**. Please upload each document separately, not as a zip, and in the following format, pdf, docx, xls, ppt. *Tip: You may upload all your Master documents in the Project Registration, but please withhold from uploading your Site-Specific documentation until you get to the SSA.*

Part E: Upload Attachments

Preview

Save

Next

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Please provide a copy of your Study Protocol or Project Description.

E2 Master Study documents and other relevant documents required for submission

This section has been included at Project Registration to ensure consistent naming of frequently required documents.

You should only upload project-wide, master documents in this section.

All documents uploaded here will be automatically be added to any subsequent ethics and/or governance application(s), as appropriate.

Do not upload Site-specific documents here. They should be uploaded with the SSA applications only.

IMPORTANT INFORMATION

- **Maximum** document size is 20MB
- **Total upload** cannot exceed 95MB. If your application exceeds this limit, please contact the research office to discuss an alternative document submission process.
- **Uploading** the same document multiple times (e.g. Protocol at E1 and E2) may cause the system to crash.

PLEASE DO NOT UPLOAD DOCUMENTS AS A .ZIP FILE. This will result in your documents not being listed correctly on any approval or acknowledgement correspondence.

You may upload any of the following document types:

- .pdf
- .docx / .doc
- .xls / .xlsx
- .ppt

Document type - please select from the list*

Study protocol

Document title - your name for the file *

ABC-1234 versus DEF-5678 Study Protocol.pdf

File Name

Size

✖ ABC-1234 versus DEF-5678 Study Protocol.pdf.pdf

88.54 kB




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
Step 11

➤ **Submit** – Proceed to the Submit page and select 'Complete Registration'.

Submit

 Preview

 Save

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When you select the Complete Registration button below, REGGS will check whether your registration is complete and if so, will generate subsequent applications depending on your responses to the registration questions.

PROJECT REGISTRATION CANNOT BE CHANGED ONCE IT IS SUBMITTED.

BEFORE YOU CLICK "COMPLETE REGISTRATION" MAKE SURE YOU CAN SEE EACH TYPE OF APPLICATION YOU EXPECT TO BE CREATED IN REGGS.


If you are submitting a HREA to a Ramsay HREC you should see "A HREA" below.

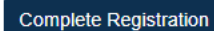
If you are submitting a Research Governance Application, EACH site selected under the Ramsay Health sites tab at Part B should be listed below.

The following applications will be generated:

SSA for each of the following Ramsay Health sites:

Border Cancer Hospital, Dr Leslie Silk (PI)

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Note: You cannot edit a Project Registration after it has been submitted.



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Site Specific Application

Proceeding to the SSA

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Step 1

- Once you have submitted your Project Registration, it will appear on your **Home Page under 'Top 5 Projects'** with an ID as follows; **2024/PID/0162**. Click on this link and you will be taken to your Project Page.

Research Applicants

This home page will list below the 5 most recently registered projects you have access to as the application owner or permitted user. Click on the project link (e.g. 2021/PID/0001) to view project details, including associated ethics and governance applications.

To register a new project, use the "New form" button below or click on the "Projects" icon above.

To continue an in-progress registration or view/manage other registered projects not listed below, please click on the "Projects" icon in the menu bar at the top of this page or use the "View all" button in the bottom right hand corner of the "Top 5 Projects" section below.

Other users - Executives/Delegates, HREC Members, External Reviewers, etc.

Depending on your role, you may have additional icons in the bar above such as 'Decision', 'Meetings' and/or 'Review'. If you have received a notification that you have an activity to view in those areas, select the related icon to access the area you require.

Create an application

+ New form	Site
+ New form	Ethics
+ New form	Authorised Prescriber Scheme

Top 5 projects

2024/PID/0162	ABC-1234 versus DEF-5678 in combination with polatuzumab-v...	Registered	12/09/2024
2023/PID/0194	PRIME - The risks of caffeine consumption via energy drinks in ...	Registered	18/09/2023
2022/PID/0064	Leslie's Test of the full system	Registered	09/05/2022

Note: The PID is the Project Identifier, e.g. 2024/PID/0162. Once you submit your Project Registration you will also be assigned an RGO identifier, e.g. 2024/RGO/0172.

Proceeding to the SSA

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Step 2

- Halfway down the page under the words **IDENTIFIER**, you will see another link which is the application for this project with an ID as follows; **2024/RGO...** Click on this link to begin your SSA.

Project > 2024/PID/0162 - ABC-1234 versus DEF-5678 in combination with polatuzumab-vedotin, as primary treatment for patients with diffuse large B-cell lymphoma, an open label randomized Nordic Lymphoma Group phase III trial.

Applications Details More information requests

All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also click on the application in the "Hierarchy" diagram opposite.

To customise your view, click on "Column chooser" below. You have the option to filter, sort and hide/show columns in accordance with your preferences.

+ New Site

Edit page description

Export CSV Search...

Column chooser

IDENTIFIER	TITLE	COMMENTS	VERSION	STATUS	OWNER	CREATED...	MODIFIED...	ORGANIS...	RELATIO...
2024/RGO/...	ABC-1234 ver...		1.00	In Progress	LS	12/09/2024	12/09/2024	Border Cance...	↑

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Page size: 10

Hierarchy History

2024/PID/0162
ABC-1234 versus DEF...

2024/RGO/0172
ABC-1234 versus DEF...

Completing your SSA

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Step 3

- **Part A – Project Wide Information** – Please answer every question on the page with a red asterisk. **If a Research Agreement is required for this study, indicate accordingly (yes/no) and nominate the status, i.e., ‘Reviewed by Research Contracts, fully executed and attached to application’.** Note: You will only have a Sponsor if your study is a Clinical Trial - all other studies do not require a Sponsor. Please select None at B5 for all other study types. For studies that do have a Sponsor, please make sure you include the name of the Local Sponsor.

Sponsor Name

Cancer Institute NSW

A14. Research Agreement *

A14.1 Is a Research Agreement required for this study? *

(If you are unsure or require further information, please contact Research Contracts at the Ramsay Health Care National Research Unit by email at RHCResearchContracts@ramsayhealth.com.au)

☒ Yes ☐ No

A14.1.2 Please advise the status of the Research Agreement *

(If you are unsure or require further information, please contact Research Contracts at the Ramsay Health Care National Research Unit by email at RHCResearchContracts@ramsayhealth.com.au)

- ☒ Reviewed by Research Contracts, fully executed and attached to application
☐ Budget fully negotiated - Agreement still under review by all Parties
☐ Currently being reviewed by all Parties - Agreement and budget not yet finalised
☐ We have not contacted Research Contracts yet (oops!)

A14.2 Has the Sponsor provided Ramsay with an indemnity? *

☒ Yes ☐ No

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Step 4

Part B – Site Team – Please fill out an entry for each member of your study team, i.e., Principal Investigator, Sub-Investigator, Clinical Trials Coordinator/Nurse/Assistant, Research Assistant. ***Please ensure you indicate whether the person is accredited to practice in a Ramsay facility, whether they are a student, the research activities they will be responsible for at site and their expertise relevant to the study.***

B2. Principal Investigator

Email *	Name	Contact phone (mobile preferred) *
<input type="text" value="silkl@ramsayhealth.com.au"/>	<input type="text" value="Dr Leslie Silk"/>	<input type="text" value="0431 555 666"/>
Position * ⓘ	Employer	Department *
<input type="text" value="Principal Investigator"/>	<input type="text"/>	<input type="text" value="Oncology"/>

B3. Describe the research activities this person will be responsible for at this site

B *I* \times_2 \times^2 Ω \vee T_x \therefore \therefore \equiv \equiv \equiv \vee \leftarrow \rightarrow

As the Principal Investigator, Dr Silk will oversee the conduct of the study at Border Cancer Hospital, participating under the coordination of the study sponsor, Elysium Pharmaceuticals Pty Ltd. PI Silk will also oversee the initial and ongoing Ethics and Governance requirements. As the PI, Dr Silk will be responsible for participant recruitment and consent, treatment, care and follow up.

B4. Describe the person's expertise relevant to this research activity they will undertake at this site *

B *I* \times_2 \times^2 Ω \vee T_x \therefore \therefore \equiv \equiv \equiv \vee \leftarrow \rightarrow

Dr Silk is a qualified medical oncologist with over 20 years experience in Clinical Trials including investigator-initiated, collaborative group and industry sponsored trials. She holds a Bachelor of Medicine - MBBS Hons from the University of Sydney and is a member of the Fellowship of the Royal Australasian College of Physicians. As previously mentioned she will be responsible for the overall conduct of the study at Site, act as the main conduit between the study sponsor and Site, oversee the Ethics and Governance requirements be responsible for the recruitment, treatment and management of all study participants.

B5. Is the PI a student? *

☐ Yes ☒ No

B6. Is the PI a Ramsay Health staff member or Accredited Practitioner at this site? *

☒ Yes ☐ No

Completing your SSA

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Step 5

Part C – Departments & Services – *Please list every Ramsay-department within your Site that will be participating in the study.* For example, a Phase I Oncology Clinical Trial would include the **Clinical Trials Unit, Day Infusion Unit, Pharmacy** (if this is operated by Ramsay), **a Ward** (should the patient require overnight admission), **Admissions Department, and Intensive Care Unit**, in the event of a Serious Adverse Event. Include a contact name and email address for the nominated personnel and provide documentation of discussions with said departments (such as a signed letter of support), please outline whether training is to be provided to staff and if so, by who and when. Please also outline whether equipment will be provided for the study and confirm this has been discussed with the Hospital beforehand.

C1. Department *

Day Infusion Unit

C2. Department Contact Name

First name

Jarnah

Last name

Miller

C3. Department Contact email address

millerjarnah@ramsayhealth.com.au

C4. Please state the study related activities required to be undertaken by this Department and the resources (e.g. staff, service/s, investigations etc) you require this department to provide . *

If any staff members / VMOs / contractors at this facility require training in order to participate in this research project please provide details here regarding who will be providing the training to Ramsay Staff/Accredited practitioners and who will bear the cost of the training.

Example: Day Infusion unit staff will be required to administer the study drugs; perform screening tests, monitor participants whilst in the Infusion unit, take regular blood samples and urine samples and administer questionnaires.

Example: Theatre staff will be required to collect data during surgery using computer equipment provided by the Trial Sponsor. Training will be provided by the Sponsor to the PI and Ramsay Theatre Staff prior to participants being enrolled in the trial. This will occur at the Site.

As the Nursing Unit Manager, Jarnah will be required to administer the study drugs; perform screening tests, monitor participants whilst in the Infusion unit, take regular blood samples and urine samples and administer questionnaires. All study-specific training will be provided by the Sponsor during the Site Initiation Visit.



Step 6

Part D – Recruitment, Records, Tissues & Data

– Please answer every question on the page based on the Patient Information & Consent Form and the assessments required in the Study Protocol. *Tip: Components that often get overlooked here include a) failure to select the study requiring access to Medical Records and access to Ramsay IT Systems other than Medical Records (if you communicate/collate study information using Ramsay's Outlook/Word & Excel, please answer accordingly), b) failure to list all forms of data being collected (questionnaires, recorded interviews, demographics), c) failure to select all the treatments, procedures, interventions being performed on a patient (don't just list the Investigational Drug, list the Standard Comparator if the study is a Randomised Controlled Trial, blood, tissue samples, radiation and imaging etc.) and d) failure to nominate whether the patient will require hospitalisation for the research project.*

Part D: Recruitment, Records, Tissue and Data

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D1. Will participants be providing written consent to participate in this research study? *

☒ Yes ☐ No

D1.1 How will participants be identified and approached? *

Participants will be identified during ward/oncology rounds or in the Investigator's private rooms and provided with a PICF for consideration. They will be invited to attend a follow up appointment and Informed Consent visit.

D1.2 Where will consent be obtained and by whom? (e.g. In Doctors' rooms, Day Oncology Unit, on Surgical ward etc.) *

Consent will be obtained by the Principal Investigator in her private rooms.

D1.3 Where will participant consent forms be kept and who will have access to them? *

A signed copy will be given to the participant, and the original will be kept in their clinical trial/patient folder which will be stored securely in a locked cupboard of the Clinical Trials Unit, only members of the Study Team will have access.

D2. Is there a numeric site enrolment target? *

☒ Yes ☐ No

D3. What is the minimum number of participants to be enrolled at this site? *

☐ No minimum target at this site

2

D4. What is the maximum number of participants to be enrolled at this site? *

☐ No maximum target at this site

4

D6. Will this project require access to a participant's medical record (including electronic databases) from this site at any stage of the research project? *

☐ Before enrolling participants

Completing your SSA

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Step 7

Part E – Site Costing & Funding

Please answer each question marked with an asterisk. If staff are providing support for your project without payment - eg collecting samples, administering questionnaires, recruiting participants, please indicate Yes at E2.

Under Invoicing Details for Research Governance Review Fees, **ensure you list all details required on this invoice, including anything specified by the Sponsor. This will typically be the details contained in research contracts.**

Part E: Site Costing and Funding

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E1.1. Will funding be provided to the Facility for the research activity at this site? *

☒ Yes ☐ No

Please provide details:

This is a Commercially Sponsored clinical trial, funding of which will be provided by the Sponsor, Elysium Pharmaceuticals Pty Ltd.

E1.2. Are there any financial costs to the Facility associated with the project which will **not** be covered by funding? *

☐ Yes ☒ No

E2. Are there any non-financial costs to the Facility (e.g. providing in-kind resources) associated with the project? *

☐ Yes ☒ No

Invoicing Details for Research Governance Review Fees

Please provide invoicing details for the payment of Research Governance Review fees.

N.B. Please ensure you list all details required to be listed on this invoice, including any Sponsor requirements.

Company Name *

Elysium Pharmaceuticals Pty Ltd

Attention to *

Douglas Hanly

Email *

douglas@elysiumpharma.com.au

Additional Email

Protocol Number/Reference *

ABC-1234

ABN *

36 003 184 889

Address *

60 George St, Marrickville NSW 2204, Australia

Phone *

Landline (61) 2556 7891

Site No (if applicable)

1

Invoicing Instructions ⓘ

Please email invoices to Douglas on the email address provided

All Governance fees are payable to the Ramsay Hospital Research Foundation.

An invoice will be generated and sent for payment once an application has been lodged.



Completing your SSA

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Step 8

Part F – Attachments, Site-Specific Documents – Here you must upload the documents that are specific to your Site. These include Patient Information & Consent Forms – **ensure you use version control in the footer, the Logo relevant to your Ramsay Site, list the Director of Clinical Services of the facility or the Ramsay National Research Office, as contact for any complaints relating to the research.** A Governance Checklist can be downloaded from our website:

<https://www.ramsayhealth.com.au/Ramsay-Research/Applying-for-Research-Governance-at-Ramsay>

Part F: Attachments – Site Specific Documents

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Please note the details entered in "Document Type" and "Document Descriptor" fields below are what will appear on the decision notification email.

For example, if "Document Type" were selected as "Participant Information Sheet" and "Document Descriptor" is entered as "Arm 1 Master version 1 dated 22 June 2021" the decision notification email will list the document as follows:
Participant Information Sheet – Arm 1 Master version 1 dated 22 June 2021

PLEASE DO NOT UPLOAD DOCUMENTS AS A .ZIP FILE. This will result in your documents not being listed correctly on any approval or acknowledgement correspondence.

You may upload any of the following document types:

- .pdf
- .docx / .doc
- .xls / .xlsx
- .ppt

The following minimum documents should be provided with your submission. Please ensure both clean and tracked changes versions are provided where applicable:

- Study Protocol
- Ethical approvals for all documents provided
- Ethical approval for Ramsay Sites to participate in trial
- CTN naming Ramsay Facility and Investigator Brochure (for unapproved products/devices)
- Pharmacy Service Form *** for all trials using Ramsay Pharmacy services **NEW**
- Master and Site Specific PICFs
- Any other patient facing HREC approved documents to be used in Ramsay Facility (eg surveys, questionnaires, advertising, data collection sheets)
- Research Contracts, Indemnities (as applicable)
- Proof of current Insurance cover: eg Clinical Trials Insurance for specific study or Medical/Professional Indemnity Insurance (confirming research is covered)
- CV and GCP for Site PI

Note: Master documents uploaded at the Project Registration form do not need to be uploaded again.

Document Title

ABC-1234 versus DEF-5678 HREA

Document Type

Ethics application (HREA or other)

File Name

✗ ABC-1234 versus DEF-5678 HREA.pdf

Document Type *

Study protocol

Document Descriptor *

ABC-1234 versus DEF-5678 Study Protocol.pdf

File Name

✗ ABC-1234 versus DEF-5678 Study Protocol.pdf.pdf



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Completing your SSA

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Step 9

Part G – Declaration – Please get the Principal Investigator to answer the question relating to ‘any affiliation, financial interest or other conflict of interest’ and then press the ‘Complete SSA’ button down the middle of the page. If the PI does not have capacity to submit the SSA, please fill in the SSA Declaration form (a copy can be provided to you from Governance) sign it, scan and email a copy to our Team with the PI Cc’d on the email and we will submit the SSA on their behalf.

Part G: Declaration

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G1.1 Is there any affiliation, financial interest or other conflict of interest that the investigators, their family members or the facility may have in the conduct of this research project or its outcomes? Please select all that apply. *

- ☐ Board Appointment
- ☐ Bonus Payment
- ☐ Conference and Travel Payment
- ☐ Consultancy
- ☐ Direct Payment
- ☐ Equipment
- ☐ Patent
- ☐ Recruitment Incentive
- ☐ Shares / Options
- ☐ Other
- ☒ No conflict of interest

G2 Declaration by the Principal Investigator Responsible for the site

By clicking the button below I confirm that:

1. the information provided is truthful and accurate to the best of my knowledge and belief and I take full responsibility for this project at this site;
2. all members of the research team at this site have the appropriate qualifications, training, experience and facilities to conduct the research as set out in this application and to deal with any contingencies related to the research
3. I will ensure all team members receive any additional relevant training as required;
4. I will not start this research project at this site until I have received confirmation of site authorisation in writing from the Research Governance Office and, that this will not be before evidence is received by them (provided by me); Ethics Committee (HREC);
5. I accept responsibility for the conduct of this research project at this site according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (as amended) and the Australian Code for the F applicable, Note for Guidance on Good Clinical Practice. If I am unable to continue as PI at this site, I will notify the National Research Unit of my proposed replacement.
6. If authorised to undertake this project at Border Cancer Hospital (this site),
 - a. I will inform the Research Governance Office of any changes to the research project (including staff/researcher changes) and receive approval for these changes prior to implementation at this site;
 - b. I will notify the Research Governance Office of any adverse events arising from this research project in accordance with Ramsay Health Care policies;
 - c. I will inform the Research Governance Office if the research project ceases before the expected date;
 - d. I will discontinue the research at this site if the HREC withdraws ethical approval and notify the Research Governance Office immediately of this withdrawal;
 - e. I will adhere to the conditions of authorisation stipulated by the authorising authority at this site including any monitoring/reporting requirements;
 - f. I will discontinue the research at this site if the authorising authority withdraws authorisation;
7. I understand and agree that project files and documents and research records and data may be subject to inspection by delegates of the authorising authority at this site (generally the Research Governance Officer) for audit an
8. I understand that personal information relating me as Principal Investigator and the other members of the research team contained in this form will be collected, held and used by Ramsay Health Care in accordance with the Ra

Name of Principal Investigator

Dr Leslie Silk



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