REGGS Ethics & Governance:
How-To Guides

Project Registration

How to Register a Project in REGGS

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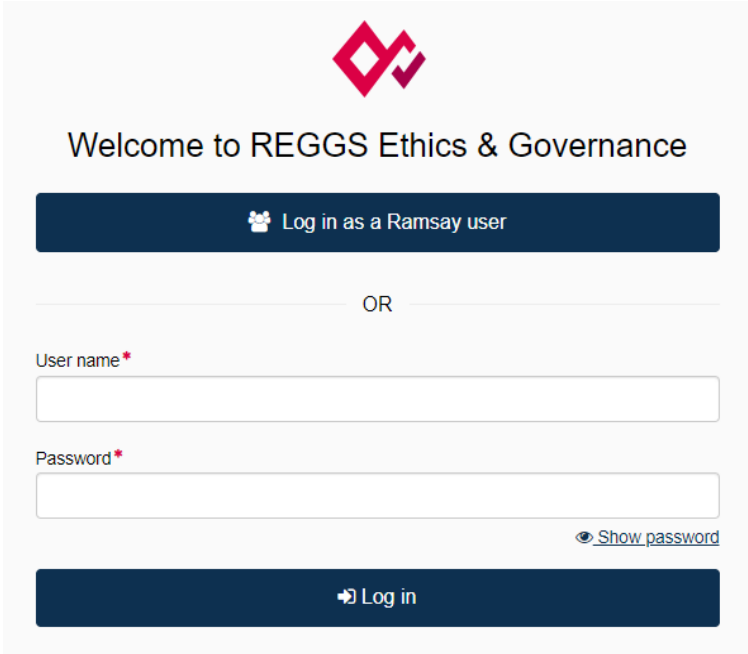
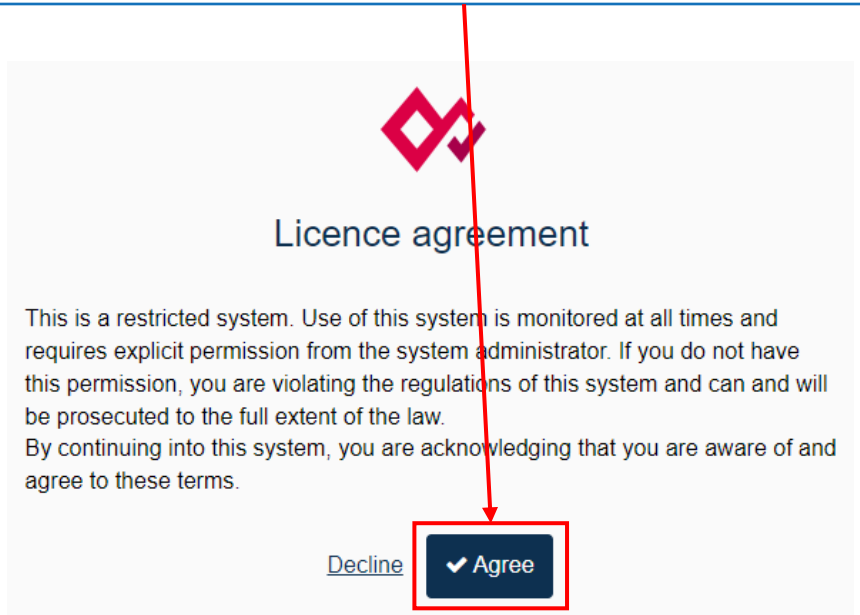
Step 1

- 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 ✔ Agree
- This will log you into your account.



Ramsay Health Care

How to Register a Project in REGGS.

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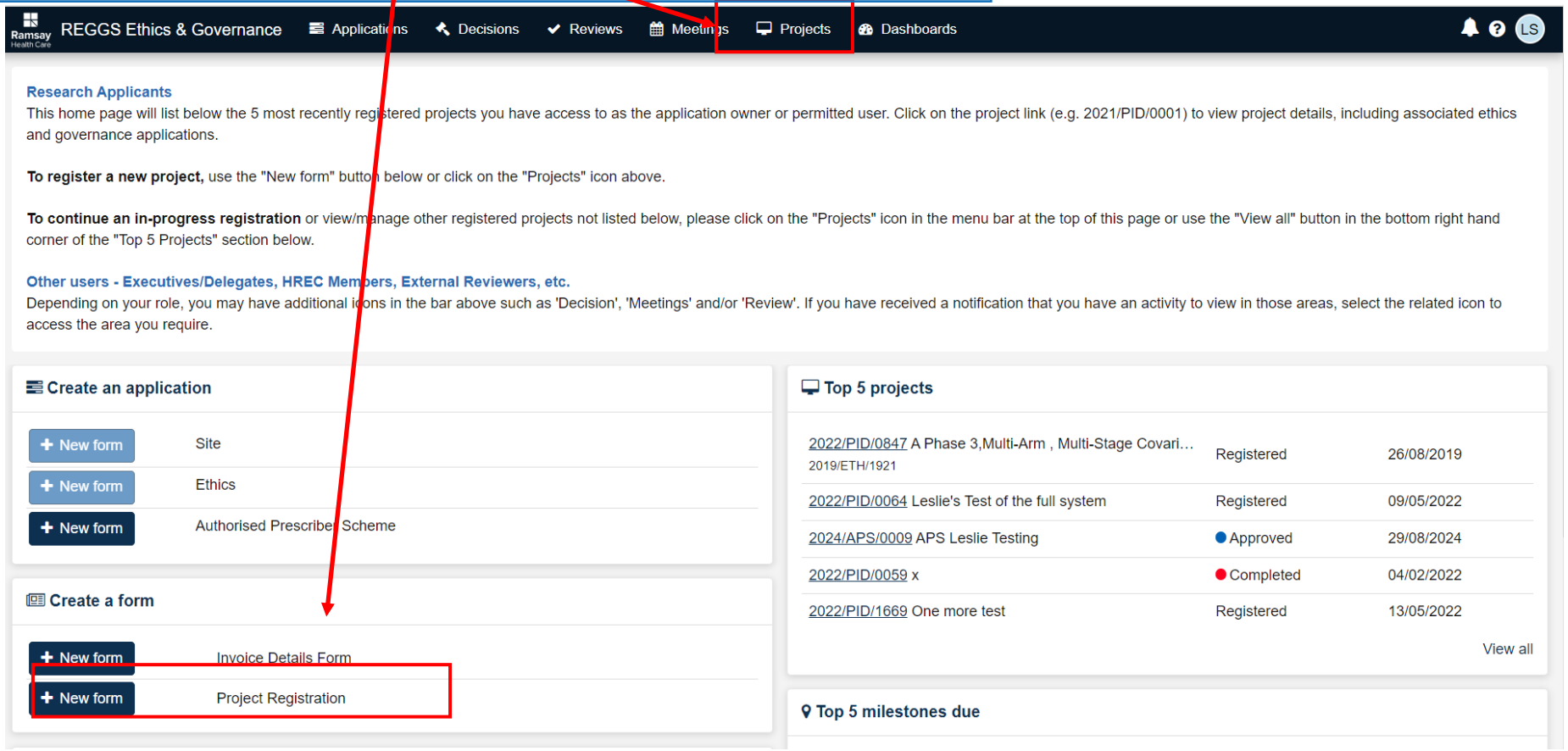
Step 3

- 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.**



How to Register a Project in REGGS

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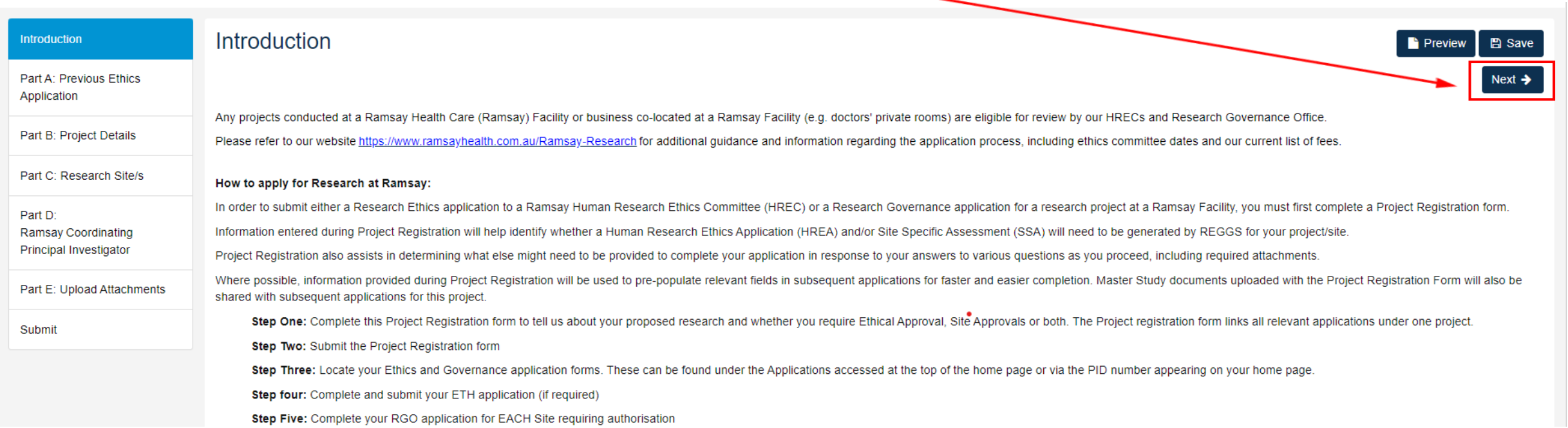
Step 5

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



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

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How to Register a Project in REGGS

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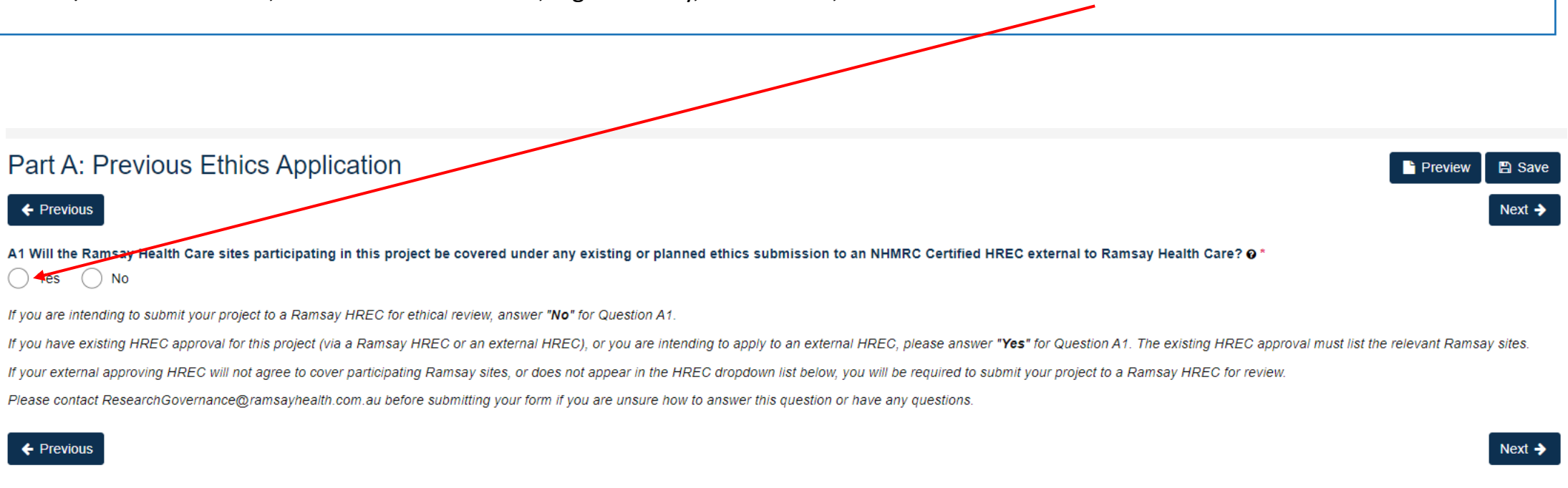
Step 6

- 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.



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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How to Register a Project in REGGS

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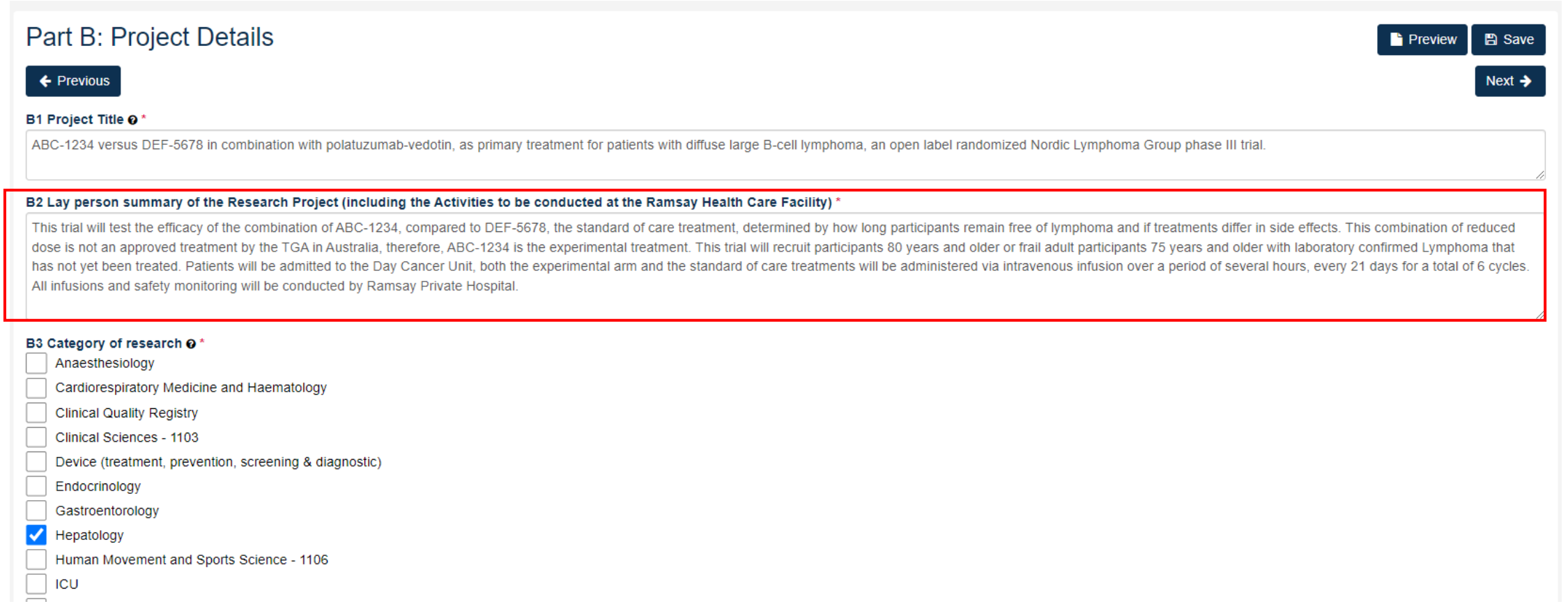
Step 7

- **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.



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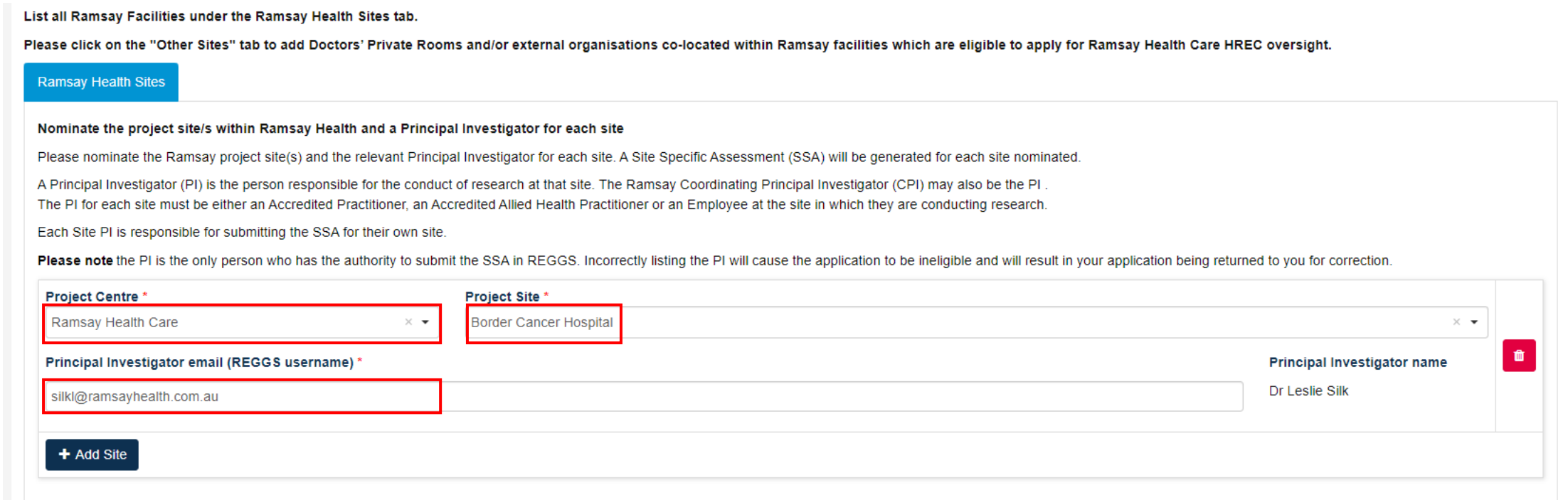
Step 8

- **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.



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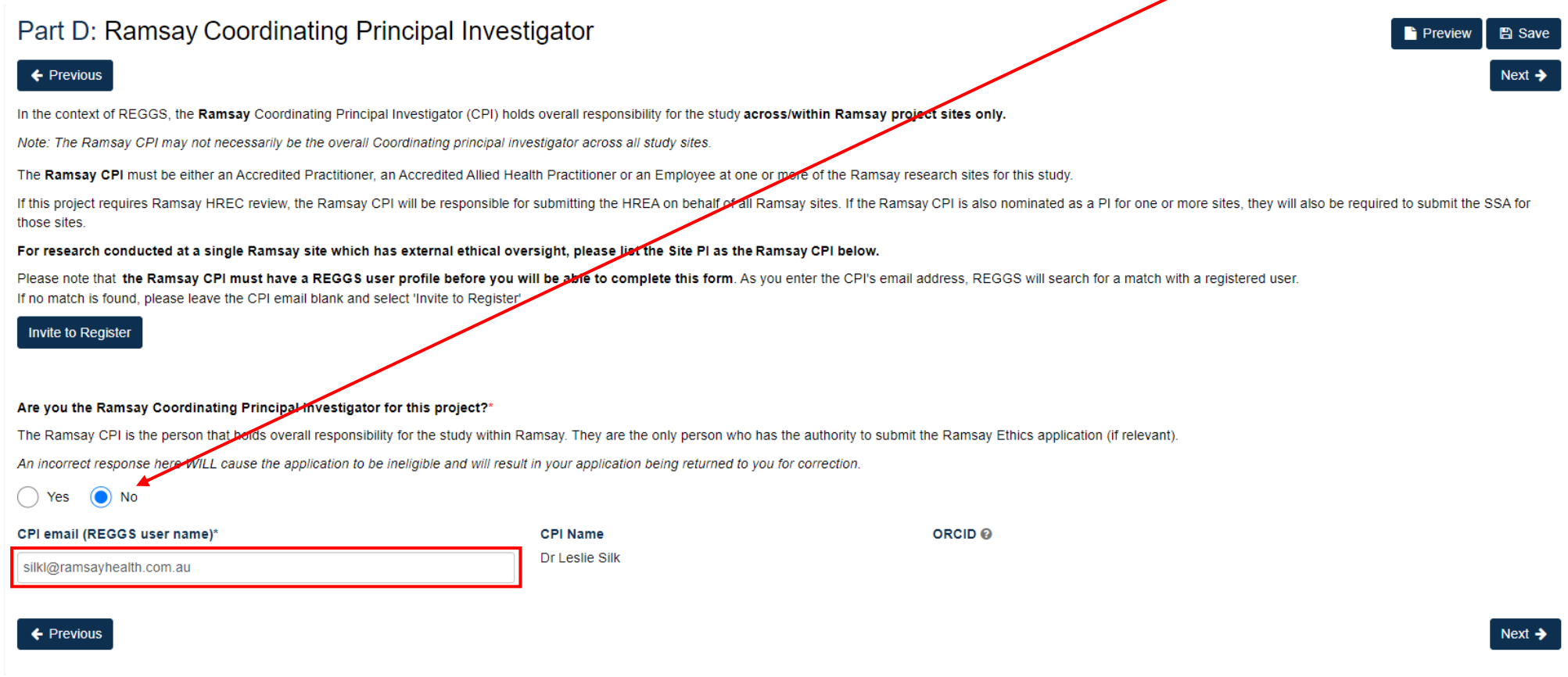
Step 9

- **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).



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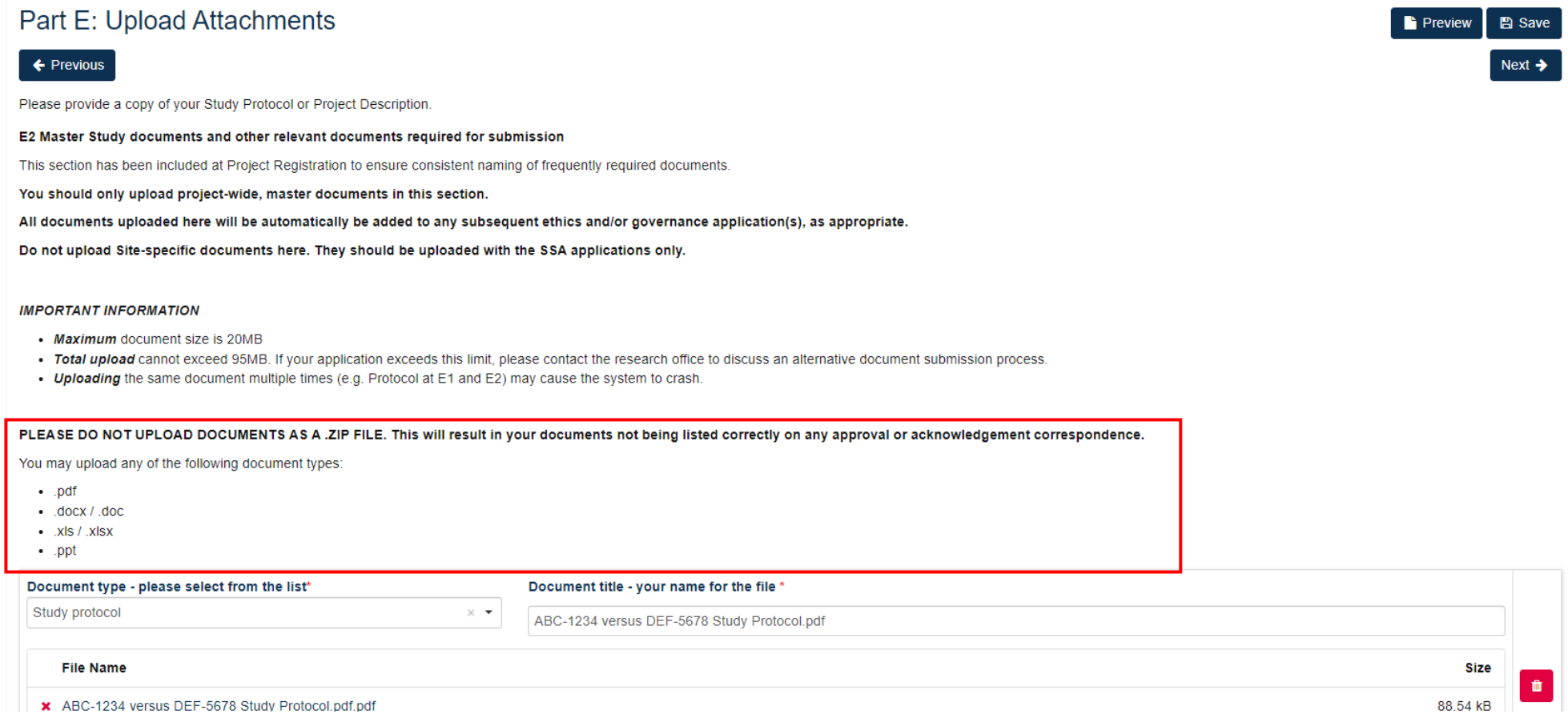
Step 10

- **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.**



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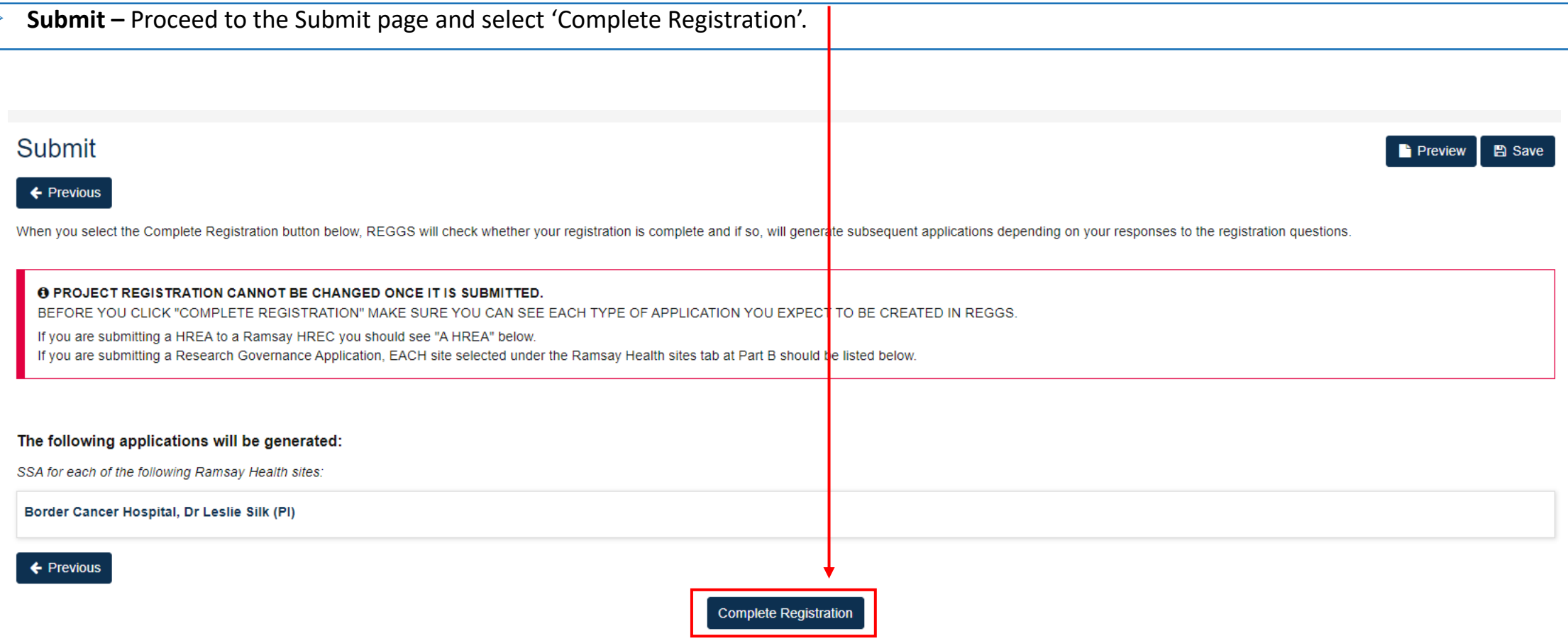
Step 11

➢ **Submit –** Proceed to the Submit page and select ‘Complete Registration’.



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

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REGGS Ethics & Governance:
How-To Guides

Site Specific Application

Proceeding to the SSA

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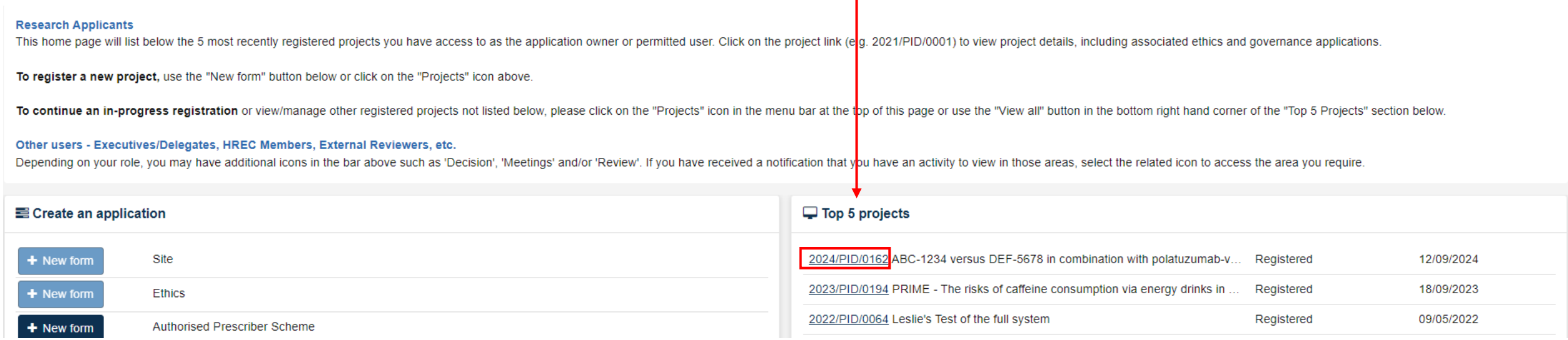
Step 1

- 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.



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.

Ramsay Health Care

Proceeding to the SSA

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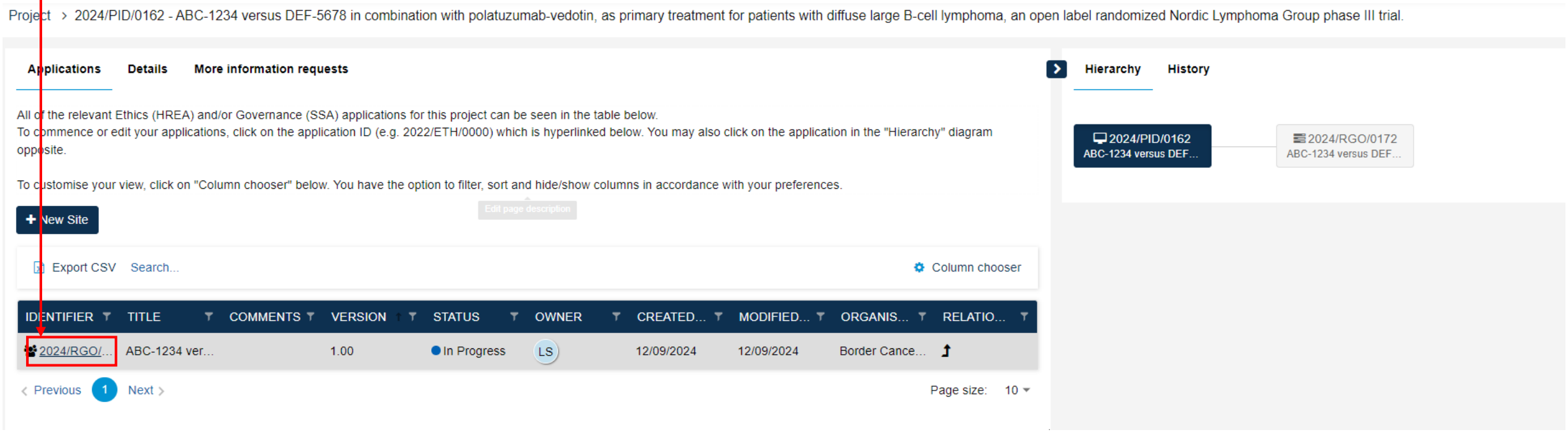
Step 2

- 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.



Ramsay Health Care

Completing your SSA

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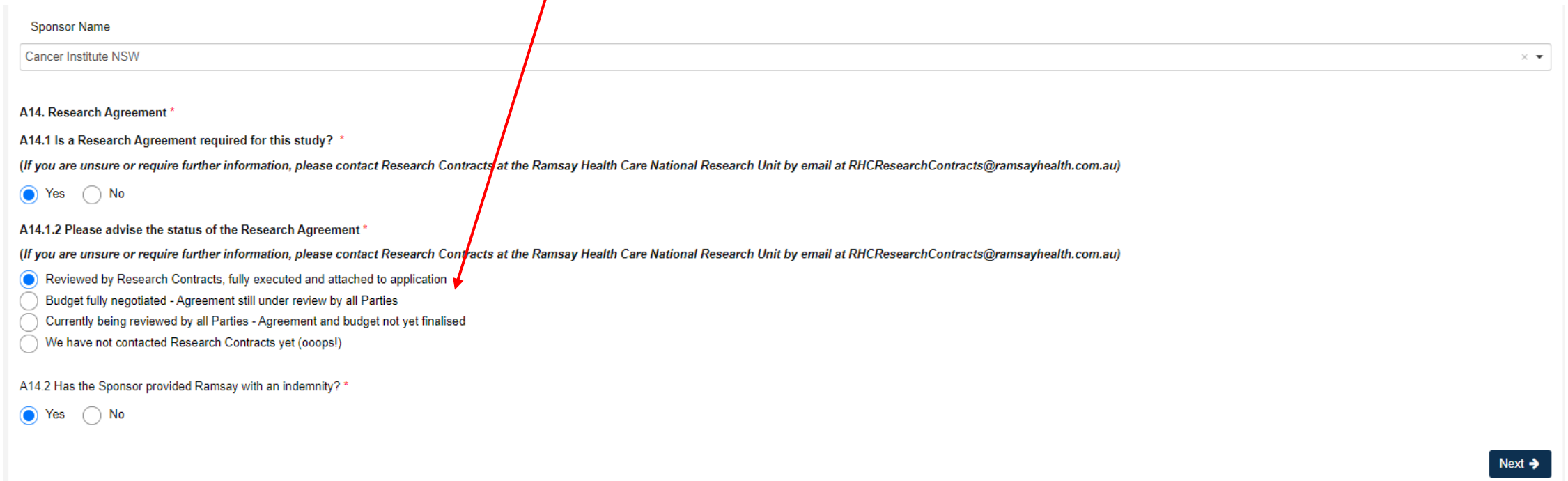
Step 3

- **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.



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Completing your SSA

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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 *
silkl@ramsayhealth.com.au

Name
Dr Leslie Silk

Contact phone (mobile preferred) *
0431 555 666

Position *
Principal Investigator

Employer

Department *
Oncology

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

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 *

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

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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.

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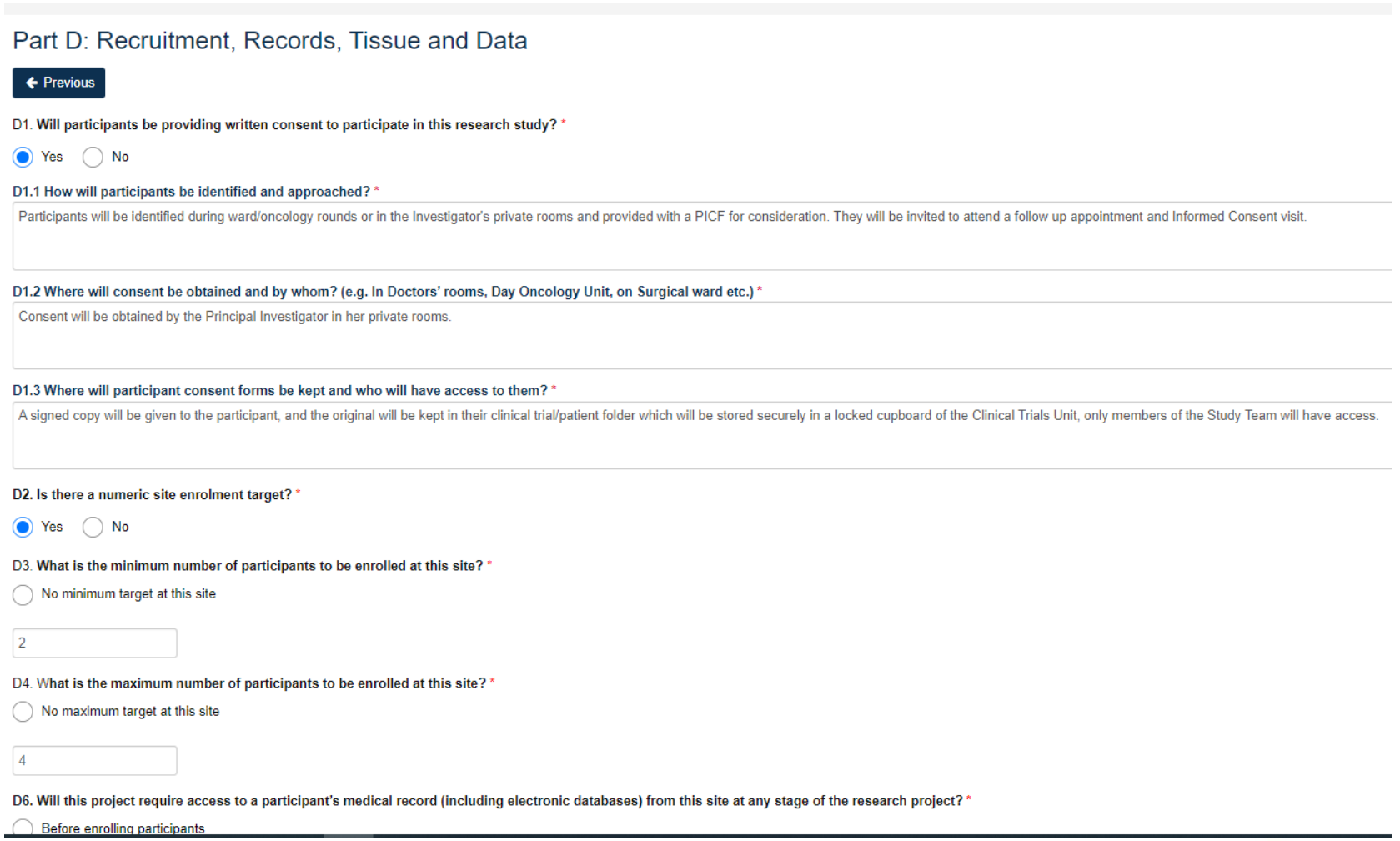
Step 6

- **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

Previous

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

Ramsay Health Care

Completing your SSA

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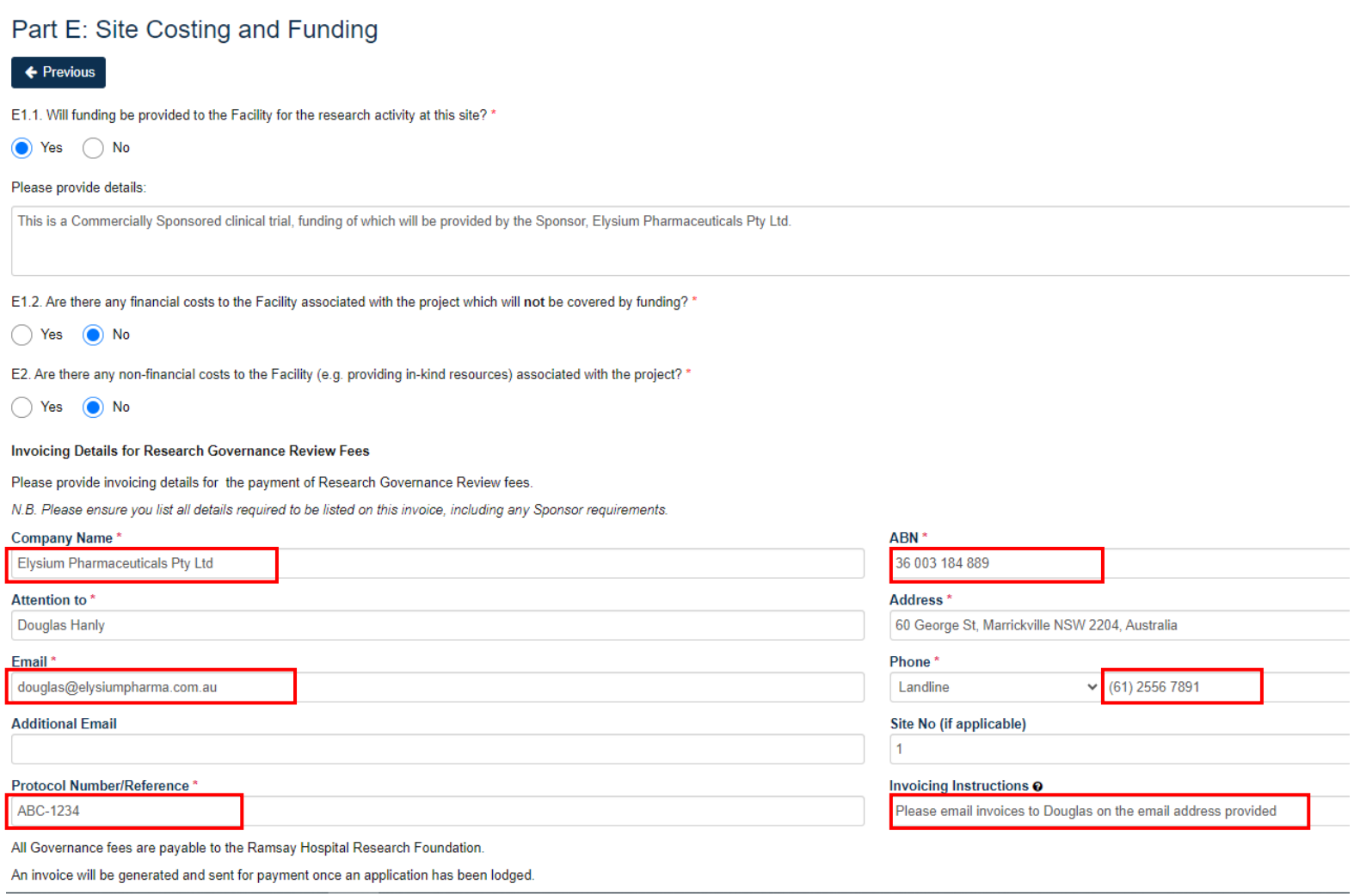
Step 7

- **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

Previous

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

ABN * 36 003 184 889

Attention to * Douglas Hanly

Address * 60 George St, Marrickville NSW 2204, Australia

Email * douglas@elysiumpharma.com.au

Phone * Landline (61) 2556 7891

Additional Email

Site No (if applicable) 1

Protocol Number/Reference * ABC-1234

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.

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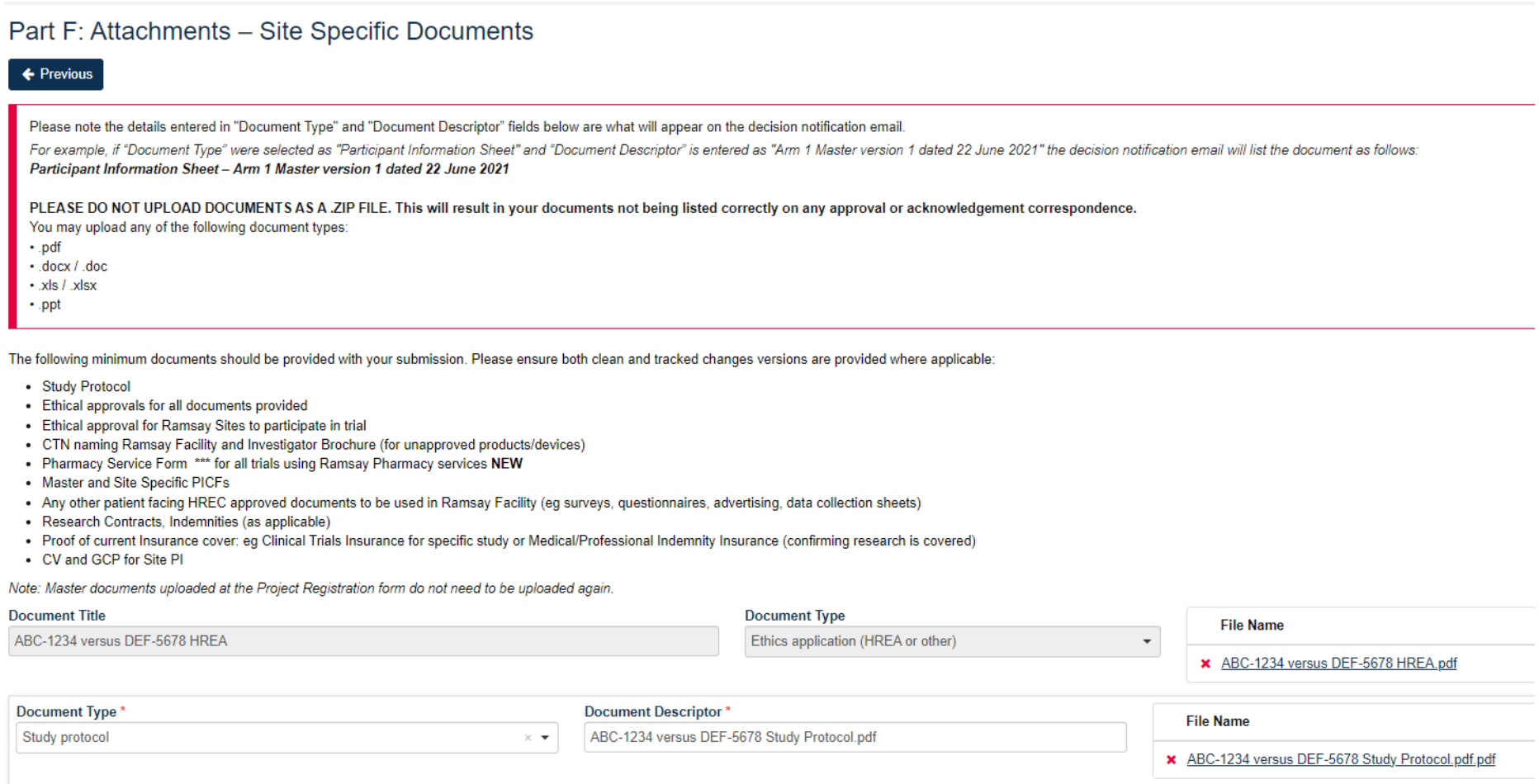
Step 8

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

Previous

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	Document Type	File Name
ABC-1234 versus DEF-5678 HREA	Ethics application (HREA or other)	ABC-1234 versus DEF-5678 HREA.pdf

Document Type *	Document Descriptor *	File Name
Study protocol	ABC-1234 versus DEF-5678 Study Protocol.pdf	ABC-1234 versus DEF-5678 Study Protocol.pdf.pdf

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Completing your SSA

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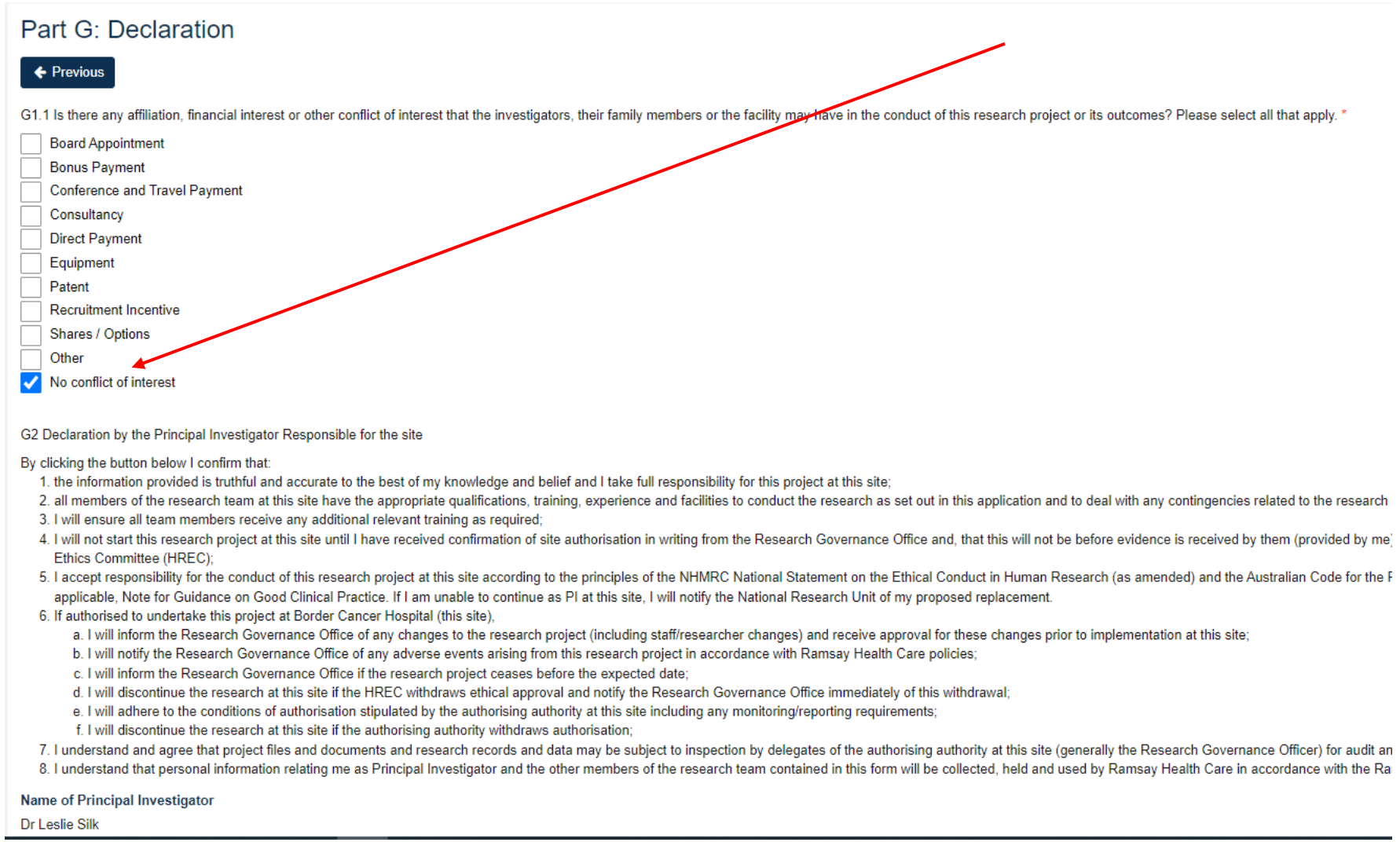
Step 9

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

← Previous

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
- [x] 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

Ramsay Health Care