DEPARTMENTAL CHECKLIST WALKTHROUGH

1. Access the department checklist project by clicking on **Projects** in your SAGE homepage.

St Vincent's Application for Governance and Ethics 🔦 Decisions 🗸 Reviews 🗎 Meeting	Projects	Dashboards		A 0 (
		SAGE				
Please view all your projects under the Project Tab - please contact research directorate@svha org auto request access to missing projects. Where appropriate, you will need to request a member of the Research Team's approval to access the project.						
Resources:			Type of submission	Current method of submission (updated Dec 22)		
 2023 HREC Closing and Meeting Dates out now The closing dates only apply to NEW HIGH RISK ETHICS APPLICATIONS. 		Ethics and Governance applications and their supporting documents (Pre-approval stage)	SAGE			
All other submissions are not reviewed during the HREC Meeting, and may be submitted outside the RGU closing dates, including. Governance submission for high-risk studies Cuality Assurance Cuality Assurance Cuality Assurance Amendment Requests and Acknowledgement Submissions ARGE User Guide SVHM Guidelines SVHM Guidelines Agreements, Checklist, Contract Submission Form, and Fee Form available here Video Tutionals for New Ethics and Governance Submissions and Post-Approval Management on SAGE			Amendment submissions including Acknowledgement & CMORT	SAGE		
			DSMB/SRC/DMC/DRC/IDSMC meeting reports	SAGE		
			Insurance certificates	Research.ethics@svhm.org.au		
			Non-Serious & Serious Breach Reports	Research.ethics@svhm.org.au		
			DSUR & Annual Safety Reports	SAE.ClinicalTrial@svha.org.au		
			SAEs	SAE.ClinicalTrial@svha.org.au		
			Site Closure/Final Reports	svhm.ResearchAnnualR@svha.org.au		
			Annual Progress Reports	svhm.ResearchAnnualR@svha.org.au		
Announcements: • 2022 SVHM Research Report out now!						

- 2. Search for the departmental checklist project by typing in **CTW** in the search box.
- 3. Open up the project by clicking the title.

ishboards	📕 🔍 🖣
	+ New Project
Nge description Video Tut	orials
Pre-Approval Process (Application Stage) Submitting a New Ethics Application Submitting a New Governance Only Application (Ethics Approved by an External (HREC) Completing Governance Application after SVHM HREC Approval Sharing an Application with Other Users Responding to a Intellipte Application Responding to Letter of Query	Post-Approval Process (Active Project Stage) Sharing an Approved Project (Ethics or Governance) Submitting an Amendment
	Column chooser
STATUS	т
Registered	
Registered	
	Page size: 100 *
	Pre-Aperoval Process (Application Stage) • Submitting a New Ethics Application (<i>Ethics Approved by an External NEEC</i>) • Completing Governance Application after SVMH KREC Approval • Sharing an Application with Other Users • Responding to an Ineligibe Application • Responding to Letter of Query STATUS Registered

4. The checklist will be created under **Milestones**.

Project > 2023/CTW00003 - Haematology Trial Unit	
Applications Details Forms Milestones	Hierarchy History
Your application status can be tracked below. You can navigate to your Ethics Application (SVH) or Governance Application (SSA) in the Hierarchy Tab (right).	D2023/CTW00003 Haematology Trial Unit

5. Click on the **milestone title** to open the checklist.

Project > 2023/CTW00003 - Haematology Trial Unit								
Applications	Details	Forms	Milestones					
Project milestones are on this page.								
Export CS	/							٩
IDENTIFIER		MILES	TONE TITLE	DETAI	_ ORGANISAT	ION STATUS	DAYS [†] REMAINING	DUE DATE
2023/CTW0000	3	E <u>Dep</u> a	artmental Checklist 1		SVHM	Pending	13 days	17/02/2023

- 6. Go through each section and complete the checklist. **Submit** when checklist has been completed.
- 7. You may download a .pdf version of the checklist by clicking on the **Preview** button.

Submit report		
		✓* View full screen
Introduction 📀	Declaration	←Previous 📑 Preview 🖉 Validate 🖹 Save Next→
Department Details	♦ Previous	
Clinical Trial Workforce and 😧 Training	Once you click on the button below, this checklist will be submitted by: Jarvis Sukamto	
Departmental Clinical Trials 😵 Policies, Procedures, and Operations	on Friday, Feb 3 2023 You can save a copy of your response by clicking on the "Preview" button on the top right corner.	
Aboriginal and Torres Strait 🥥 Island (ATSI) People in Clinical Trials	✔ Previous Submit	
Trial Participants S Engagement and Feedback		
Declaration 📀		
Submit report		✓ View full screen
Department Details	Clinical Trial Workforce and Training	← Previous Preview O Validate 🖾 Save Next→
Clinical Trial Workforce and	General Questions	
Training	Are there position descriptions for Clinical Leaders include safety and quality roles/responsibilities related to clinical trial services? • Yes No	IF YES, PLEASE UPLOAD EVIDENCE OF EMPLOYMENT RECORDS •
Departmental Clinical Trials 😢 Policies, Procedures, and Operations	This field is required	Crop files to attach, or browse
Aboriginal and Torres Strait 🤡 Island (ATSI) People in Clinical Trials		+ Add Another
Trial Participants 8 Engagement and Feedback	Do you have employment records that detail the skills and competencies required of the individuals undertaking clinical trials? ● · ○ tree > No The test are required	IF YES, PLEASE UPLOAD EVIDENCE OF EMPLOYMENT RECORDS
Declaration 🥝		Drop files to attach, or <u>browse</u>
		+ Add Another