Checklist of Required Documents

Tick	Documents required for the SSA Form	Notes
Project Registration Form		
	Original HREC approval noting when study was first approved by the HREC	Required.
	HREC Approval Letter/s for all current versions of documentation	Required. Copies of all documentation listed on the HREC Approval Letter/s
	Study Protocol – clean version	Required. As noted on the HREC Approval Letter.
	Study Protocol – tracked version	If any changes from the previously approved version.
	Study Protocol – administrative memo	If available.
	Participant Information Consent Form - Approved Master Versions	Required, unless Waiver of Consent is granted. Note this should be reflected on HREC approval.
Experimental product (Only required when unapproved products/ unapproved indication)		
	Investigator's Brochure – Clean Version	Required.
	Investigator's Brochure – Tracked version (if applicable)	If any changes from the Previous approved version.
Site Specific Application		
	SSA Application Form	Required. Generates upon submission of SSA
Part A: Project Wide Information		
	HREC Approval Letter approving the Ramsay Site	Required. Must list the Ramsay Site is listed on the Approval.
Experimental product (Only required when unapproved products/ unapproved indication)		
	CTN/ CTX Acknowledgement – with specific Ramsay Site listed	Ensure that the Ramsay Site is listed on the Acknowledgement. This should be acknowledged by the TGA. If in draft, you will be required to provide the final copy to the NRU.
Legal considerations and Indemnities		
	CTRA and/or MTAA - Ramsay Approved Version	Required for all Commercially Sponsored Clinical Trials and some Collaborative Group Clinical Trials Please contact Research Contracts in the first instance for our templates (RHCResearchContracts@ramsayhealth.com.au)
	Memorandum of Understanding, Service Level Agreement, or equivalent document	Required for some Commercially Sponsored Research Please contact Research Contracts in the first instance for clarification and our templates (RHCResearchContracts@ramsayhealth.com.au)
	Research agreement	Required for some Collaborative Group; Not for Profit entity; Medical Research Institute; University; and Investigator-initiated trials. May be required if payments to Ramsay Health Care come from the funding of the project. Please contact the Research Contracts team in the first instance for clarification and our templates (RHCResearchContracts@ramsayhealth.com.au)

Checklist of Required Documents

	MTAA standard Indemnity – indemnifying Ramsay Health Care	Required for all Commercially Sponsored Clinical Trials For any enquiries, please contact the NRU (ResearchGovernance@ramsayhealth.com.au)
	MTAA Standard Indemnity – indemnifying the Principal Investigator	Required for all Commercially Sponsored Clinical Trials For any enquiries, please contact the NRU (ResearchGovernance@ramsayhealth.com.au)
Part B: Site Team		
	CV of each research team member	Required for Site Principal Investigators, Associate Investigators and Sub-Investigators Required for non-Ramsay research team members Ramsay staff can upload a copy to their user profile
	GCP of each research team member	If clinical trial: Required for Site Principal Investigators, Associate Investigators and Sub-Investigators Required for non-Ramsay research team members Ramsay staff can upload a copy to their user profile
Insurance		
	Proof of the current insurance cover (e.g. a Certificate of Currency)	Clinical Trials Insurance policy for the study required for all Commercially Sponsored Clinical Trials Principal Investigator's Medical Malpractice Policy that covers research activities required for all un-sponsored Clinical Trials or research
	Proof of insurance for any students wishing to undertake the research	Required if the study is a student project For any enquiries, please contact the NRU (ResearchGovernance@ramsayhealth.com.au).
	Letter of support from academic supervisor for the study	Required if the study is a student project. For any enquiries, please contact the NRU (ResearchGovernance@ramsayhealth.com.au).
Part C: Departments and Services		
	Documentation of discussions with the relevant groups or operation unit (e.g. signed letter of support or email)	This is not required but will aid the site's CEO in determining the capacity of the facility to support the research project
Part D: Recruitment, Records, Tissue and Data		
	PICF Site Specific Clauses document	If any.
	Participant Information Consent Form – Site Specific – clean version	Required for multi-site study using site specific forms Please ensure that the DCS of the specific Ramsay Facility (or equivalent individual) or the Ramsay National Research Office is listed as contact for any complaints relating to the research.
	Participant Information Consent Form – Site Specific – tracked version	Tracked changes from the approved master version and including any HREC approved site-specific clauses
	Master patient-facing documents to be used within the Ramsay Facility	Require all documents appearing on the HREC approvals. Eg diaries, questionnaires, PROMS, surveys, instructions

Checklist of Required Documents

	Site specific patient-facing documents to be used within the Ramsay Facility – clean and tracked versions	Require all documents appearing on the HREC approvals. Eg diaries, questionnaires, PROMS, surveys, instructions

When preparing your Site- specific PISCFs:

Please note that an internal Ramsay person who is not directly involved in the research must be listed as a contact for complaints on the PISCF (e.g. Facility Director of Clinical Services or member of the National Research Unit).

To obtain Ramsay Logos and details for the Director of Clinical Services at a Facility, please contact the National Research Unit at ResearchGovernance@ramsayhealth.com.au

Local Governance Office details for Site PICFs are:

Research Administration Manager
National Research Unit
Ph: (02) 9433 3854
Email: ResearchGovernance@ramsayhealth.com.au