CTN Requirements for Clinical Trials within Ramsay Facilities

All research studies involving "unapproved" therapeutic goods are required to notify the TGA under either the CTN or CTX scheme.

1. CTN / CTX Overview

The **CTN scheme** is a notification scheme only; the TGA do not review or evaluate any data at the time of submission, however the online CTN form must be submitted before the trial sponsor can supply the 'unapproved' therapeutic goods in the trial.

The **CTX scheme** is an evaluation process and involves the review of relevant, but limited, scientific data (which may be preclinical and early clinical data) by the TGA prior to the start of a trial. This predominantly applies to therapeutic goods that are in the early stages of development.

2. When is Ramsay facility required to be listed on a CTN?

A trial in which an experimental procedure is undertaken (e.g. device insertion) or experimental drug is administered (e.g. oral or infusion) within a Ramsay facility area such as day oncology unit **must** list the facility as a study site on the CTN notification.

This requirement applies if **any** study activity will be performed within the facility area (e.g. infusions, bloods, etc.), even if the study is being predominantly conducted by a third party trial coordinator collocated at the facility but not operated or owned by Ramsay Health Care.

A copy of the CTN must be provided as part of a Ramsay Research Governance application.

3. When is Ramsay facility *not* required to be listed on a CTN?

If the procedure being undertaken is routine and part of normal clinical care (e.g. colonoscopy) but has a research component (e.g. additional data is collected during the procedure), the CTN is not required to list the Ramsay facility.

Similarly, if an oral drug is being administered on premises external to Ramsay (e.g. a consultant's private rooms or a leased premises within the hospital building), the Ramsay facility is not required to be listed on the CTN notice.

4. Who should I list on a CTN as the Approving Authority?

Please see table **below** for guidance on how to complete the "Approving Authority Details":

Approving Authority Details	
Approving Authority Name	***Please insert the name of the facility (e.g. "Peninsula Private Hospital" or "St George Private Hospital") here.*** ***Please note the CTN does not need to list the operating entity name (e.g. "Ramsay Health Care Australia Pty Ltd trading as…"), unlike CTRAs or indemnities.***
Contact Officer	***Please list the Facility CEO/DCS here unless otherwise advised by your Facility. The Clinical Trials Coordinator / Manager should not be listed as a contact on the CTN.***
Position	

Contact Number	
Email address	

In circumstances where a third party is operating a trial but there will be study drug or an experimental device administered within a Ramsay Hospital, Ramsay is required to be listed as separate site on the CTN.

An example of how this might be done is below:

Sites

Site	Site Address, Location	Expected Site Start Date	Principal Investigator Name	Principal Investigator Contact Phone Number	Principal Investigator Contact Email	HREC Name, Code	HREC Contact Officer, Position	HREC Contact Phone	HREC Contact Email	Approving Authority Name	Approving Authority Contact Officer, Position	Contact Phone	Contact Email
Greenslopes Private Hospital	Newdegate Street, Greenslopes, 4120, QLD	18/08/2019	Kenneth O'Byrne			Ramsay Health Care QLD HREC, EC00161	Julie Greaves, Ethics Secretary	0733947819	GreavesJ@ramsayhealth.com.au	Ramsay Health Care Australia Pty Ltd Trading As Greenslopes Private Hospital	Chris Went, Chief Executive Officer	0733947111	WentC@ramsayhealth.com.au
Gallipoli Medical Research Foundation	Greenslopes Private Hospital, Newdegate Street, Greenslopes, 4120, QLD	18/08/2019	Kenneth O'Byrne			Ramsay Health Care QLD HREC, EC00161	Julie Greaves, Ethics Secretary	0733947819	GreavesJ@ramsayhealth.com.au	Gallipoli Medical Research Foundation	Miriam Dwyer, Chief Executive Officer	0733947284	DwyerMiriam@ramsayhealth.com.au

In this example, Gallipoli Medical Research Foundation are operating a trial which requires partial involvement from Greenslopes Private Hospital. As such, the CTN lists both Gallipoli Medical Research Foundation and Greenslopes Private Hospital as separate study sites for this trial.

5. Useful Information

For further information and guidance, please refer to the CTN user guide or Clinical Trials sections of the TGA website.

6. Questions?

If you have any questions in relation to CTN requirements, please contact the Ramsay National Research Unit at ResearchGovernance@ramsayhealth.com.au.