CLINICAL TRIAL SITE NOTIFICATION

This form only needs to be completed for a clinical trial site **at which trial participants are required to stay overnight** or longer for monitoring purposes as a result of receiving the study medication.

Note: Only one form is required to be submitted for each site. If the site has been notified on Medsafe's webpage, there is no need to resubmit this form unless you need to notify any changes.

Site name	
Street address	
Name of Site Contact Person	
Telephone number	
Mobile phone number	
Email	

Check the box appropriate to your site:

☐ This clinical trial site is located within a hospital that provides full emergency response services for the site.

OR

☐ There is a formal agreement or arrangements to provide full emergency response services for patients at the site in the event of a clinical emergency or Critical Incident during a clinical trial.

All boxes below must be able to be completed for the site:

☐ The clinical trial site has round-the-clock emergency qualified and trained staff on duty during the conduct of a clinical trial.

☐ The clinical trial site has Critical Incident procedures in place to ensure the safe care of trial participants.

☐ There are Critical Incident training, refresher courses and rehearsals for staff.

☐ There are audit processes for managing Critical Incident procedures and for reviewing and documenting the adequacy of other procedures and equipment.

Declaration

I declare that, to the best of my knowledge, the information provided in this form is correct and complete.

Signature of Responsible Person (eg, the site manager) at the Clinical Trial site *Date*

Note: An electronic signature, or typing your name, are also acceptable.

Name:

Position:

Submit the completed notification form to:

Email: askmedsafe@moh.govt.nz

and put "Attention: Clinical Trials Co-ordinator" in the subject line.