



# Protocol Amendment Tracking Template

## Purpose

A formal, documented process for protocol amendments will provide an audit trail and compliance with GCP. This template provides a history of protocol amendments and ensures accurate version control.

Study name			
Grant ID number		Trial ID number	
Principle Investigator [Name and contact details]			
Primary contact person [Name and contact details]			
Protocol title			
Electronic location of protocol [File folder name and location]			
Protocol naming convention [Enter agreed format e.g. Study acronym, ethics protocol number, date, [i.e.: CHEST.O.I.YYYY-MM-DD]]			

## Human Research Ethics Committee (HREC): Primary Contacts

Site Name	Contact name, role and contact details

## Protocol Tracking: Amendments and Ethics Submissions

Date submitted	To HREC (Name)	Nature of amendment	Date received	Revised protocol name /number

[Add extra columns as required e.g. for multi-site or multi-Institution trials]