Clinical Trial Handover Form

HREC Ref:	*This is the unique HREC reference number*
SSA Ref:	*This is the unique SSA reference number*
Protocol:	*Protocol Number followed by full title*
Current Version:	Version x dated xx-xxx-2016. Approved by HREC on: xx-xxx-2016
Sponsor:	
CRO:	*If applicable*
CRA:	*Name, location and contact details (email and mobile phone)*
Site Number:	*Include Investigator Number if this is applicable*
Trial Status:	*Eg Open to Recruitment, Awaiting SIV, In Follow up*
Patient Population:	
Number of Patients:	*X* recruited at site (Target: y). z patients recruited overall (Target: a)
Primary Endpoint:	
HREC:	*Name and contact details of the HREC.* Initial Approval Date:
Amendments:	*Include details of amendments received and progress such as submission dates, approval dates and reasons why we haven't yet submitted (eg waiting for hard copies of the protocol).*
Annual Report:	Next report due: xx-xxx-2016 Last report submitted: xx-xxx-2016
Pharmacy:	*Include name of pharmacy and contact details of trial pharmacist*
Investigational Product:	*Include name, route of administration, dosage, how often dispensed, dispensing procedure (if different from standard). Include most common adverse events, any prophylactic medication required (eg antiemetics) and location of important safety information (eg dosing modification guidelines, prerequisites for dosing etc).*
Comparator Drug(s):	*Include same information as for IMP for each comparator drug. In addition, state whether compactor drug is provided by Sponsor or via the PBS.*
IXRS:	*Provide details of IXRS system, location of IXRS manual and how to contact the helpdesk. For IWRS, include website address. For IVRS, include telephone number.*
SAEs:	*Include method of reporting SAEs (eg eCRF, paper form), location of form and completion instructions with submission email or fax number if not on the form.*

AEs of Special Interest:	*List any AEs of special interest and summarise reporting timelines, how to report and other relevant information.*
SUSARs:	*Provide SUSARs format and location (if electronic, who has access to these, website address etc).* Last line listing submitted to HREC on: xx-xxx-2016
Local Lab	*Include name, contact details of lab staff. Include any study specific information that might be important (eg list of tests performed at local lab).*
Central Lab:	*Include name, location of lab manual, contact details of lab staff, location of lab kits, how to order more kits, how reports are received (eg fax, web portal, email), date of last kit order or if automatic resupply.*
Central Lab Courier:	*Include name of courier, how to book, fax/phone/email for booking, location of waybills, shippers declarations, packaging material etc*
Radiology:	*Name of radiology provider, location, contact details, booking procedure*
Central Radiology	*Include name of radiology provider, location of radiology manual, contact details of central radiology, how to transmit images, how reports are received (eg fax, web portal, email) etc*
eCRF:	*Website address of eCRF, location of eCRF guidelines, timelines for eCRF entry, any tips and hints not included in the guidelines*
Screening/Randomisation:	*Include any study specific requirements for screening or randomisation such how and when to enrol patients in the study, details of eligibility forms, explanations of anything that is not clear from reading the protocol.* Current PICF: Version x dated xx-xxx-2016 Approved on: xx-xxx-2016
Add additional clinical trial specific information	
Patient #*xxxx*:	DOB: xx-xxx-19xx Treating Doctor: Date of IC: xx-xxx-2016 Date of Randomisation: xx-xxx-2016 Last Visit: *Name and date* Next Visit: *Name and date* Allergies/Intolerances: Nil known *Brief narrative explaining any concerns with this patient such as work schedule, communication issues, requirements for transport, SAEs, ongoing AEs, problems with compliance etc*

Name Outgoing Clinical Trial Team Member performing handover:	

Signature:	
Date:	

Name Incoming Clinical Trial Team Member receiving handover:	
Signature:	
Date:	