

## RCH RESEARCH GOVERNANCE      AUDITING REPORT

<b>HREC Reference</b>	
<b>Protocol Name</b>	
<b>Type of Study</b>	
<b>Department</b>	
<b>Date of visit</b>	
<b>Auditor name</b>	
<b>Date of Report</b>	
<b>Date of Revision</b>	
<b>COMMENTS:</b>	

<b>I.      STUDY PERSONNEL</b>		
<b>Role in study</b>	<b>NAME</b>	<b>Met with Auditor?</b>
<b>Principal Investigator</b>		YES <input type="checkbox"/> NO <input type="checkbox"/>
		YES <input type="checkbox"/> NO <input type="checkbox"/>
		YES <input type="checkbox"/> NO <input type="checkbox"/>
		YES <input type="checkbox"/> NO <input type="checkbox"/>
		YES <input type="checkbox"/> NO <input type="checkbox"/>
<b>Discrepancies with ERD database:</b>		
<b>COMMENTS:</b>		

<b>II.      STUDY DOCUMENTS</b>						
	Document	Version #	Version Date	Approval Date	Present in Study File?	
					YES	NO*
1	Current protocol				<input type="checkbox"/>	<input type="checkbox"/>
2	Current ICF - participant				<input type="checkbox"/>	<input type="checkbox"/>
3	Current ICF - parent				<input type="checkbox"/>	<input type="checkbox"/>
4	Superseded protocol				<input type="checkbox"/>	<input type="checkbox"/>
5	Superseded ICF – participant				<input type="checkbox"/>	<input type="checkbox"/>
6	Superseded ICF – parent				<input type="checkbox"/>	<input type="checkbox"/>
7	Approved ads/ letter for patients				<input type="checkbox"/>	<input type="checkbox"/>
8	All significant <sup>#</sup> correspondence with the ERD, including Approval certificates and initial application for approval				<input type="checkbox"/>	<input type="checkbox"/>
9	Accurate and current documentation of task delegation to staff				<input type="checkbox"/>	<input type="checkbox"/>
10	Other significant correspondence (documenting decisions, changes or important discussions)				<input type="checkbox"/>	<input type="checkbox"/>
11	Accurate and current documentation of training and qualifications				<input type="checkbox"/>	<input type="checkbox"/>
<b>COMMENTS (*Any 'NO' response requires comment):</b>						

#significant correspondence is that which documents decisions or changes to the study.

<b>III. STUDY DOCUMENTS - FINDINGS</b>		<b>YES*</b>	<b>NO</b>
1	Approved documents were used prior to approval date	<input type="checkbox"/>	<input type="checkbox"/>
2	Superseded documents have been used	<input type="checkbox"/>	<input type="checkbox"/>
3	Discrepancy between versioning of study documents and approved version	<input type="checkbox"/>	<input type="checkbox"/>
4	Unapproved documents are in use or in study file	<input type="checkbox"/>	<input type="checkbox"/>
5	Study documents are incomplete or cannot be located by the study team	<input type="checkbox"/>	<input type="checkbox"/>
6	Important study documents are inaccessible to some members of the study team	<input type="checkbox"/>	<input type="checkbox"/>
7	The study approval lapsed due to an overdue annual report	<input type="checkbox"/>	<input type="checkbox"/>
<b>COMMENTS</b> (*Any 'YES' response requires comment):			

<b>IV. STUDY PARTICIPANTS</b>		<b>YES</b>	<b>NO*</b>
1	Commencement date of the study recruitment:		
2	Patient numbers approved to recruit:		
3	Patient numbers recruited:		
4	Expected completion date:		
5	Accurate and current Log of enrolled participants' study IDs, in order of enrolment and recording their current status	<input type="checkbox"/>	<input type="checkbox"/>
6	Accurate and current Log of participant names with corresponding study IDs	<input type="checkbox"/>	<input type="checkbox"/>
7	A current signed approved ICF is present for every participant	<input type="checkbox"/>	<input type="checkbox"/>
<b>COMMENTS</b> (*Any 'NO' response requires comment):			

<b>V. STUDY DATA MANAGEMENT</b>		<b>YES</b>	<b>NO*</b>
1	The study electronic documents are appropriately backed-up to avoid loss	<input type="checkbox"/>	<input type="checkbox"/>
2	The study data are regularly backed-up to avoid loss.	<input type="checkbox"/>	<input type="checkbox"/>
3	Hardcopy study data and documents are stored in a secure area, accessible only by authorised persons, maintaining confidentiality.	<input type="checkbox"/>	<input type="checkbox"/>
4	Electronic study data and documents are password protected, accessible only by authorised persons, maintaining confidentiality.	<input type="checkbox"/>	<input type="checkbox"/>
<b>COMMENTS</b> (*Any 'NO' response requires comment):			

<b>VI. STUDY TEAM MANAGEMENT</b>		<b>YES</b>	<b>NO*</b>
1	Each change of Investigator has been reported to the ERD	<input type="checkbox"/>	<input type="checkbox"/>
2	Staff have all completed the online declaration of their familiarity with the <i>RCH Investigators Responsibilities in Research Procedure</i>	<input type="checkbox"/>	<input type="checkbox"/>
3	All staff are appropriately familiar with the protocol	<input type="checkbox"/>	<input type="checkbox"/>
4	All members of the research team have appropriate training, qualifications and/or experience to conduct their study related duties	<input type="checkbox"/>	<input type="checkbox"/>
5	The PI is providing appropriate oversight of all aspects of the study	<input type="checkbox"/>	<input type="checkbox"/>
<b>COMMENTS</b> (*Any 'NO' response requires comment):			

<b>VII.</b>	<b>PROCESSES</b>	<b>YES</b>	<b>NO*</b>
1	The study is being conducted in accordance with the approved protocol (For example: -Only data, samples and patients are being used as described in the approved protocol. -All the protocol specified procedures are being followed. -Recruitment is being conducted as described in the approved protocol.	<input type="checkbox"/>	<input type="checkbox"/>
2	Significant protocol departures have been reported to ERD	<input type="checkbox"/>	<input type="checkbox"/>
3	Adverse incidents/ SAEs have been reported to the ERD & other bodies as appropriate	<input type="checkbox"/>	<input type="checkbox"/>
4	Complaints have been handled per the <i>RCH Research Complaints Policy</i>	<input type="checkbox"/>	<input type="checkbox"/>
5	Other issues regarding compliance with research policies and guidelines have been escalated	<input type="checkbox"/>	<input type="checkbox"/>
6	Only payments preapproved by the ethics committee have been made to participants	<input type="checkbox"/>	<input type="checkbox"/>
7	For a clinical trial of an investigational product: Is the trial being conducted in compliance with ICH-GCP? ( <input type="checkbox"/> NA)	<input type="checkbox"/>	<input type="checkbox"/>
<b>COMMENTS</b> (*Any 'NO' response requires comment):			

<b>VIII. RECORD REVIEW</b>							
Subject ID:		Apparent eligibility issue	Apparent consent issue	Unreported significant protocol departure	Unreported event	Inadequate documentation of an event	Data discrepancy
From date:	Initial ICF version: Date signed:	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>
To date:	Current ICF version: Date signed:	<b>COMMENTS</b> (*Any 'YES' response requires comment):					
Subject ID:		Apparent eligibility issue	Apparent consent issue	Unreported significant protocol departure	Unreported event	Inadequate documentation of an event	Data discrepancy
From date:	Initial ICF version: Date signed:	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>
To date:	Current ICF version: Date signed:	<b>COMMENTS</b> (*Any 'YES' response requires comment):					
Subject ID:		Apparent eligibility issue	Apparent consent issue	Unreported significant protocol departure	Unreported event	Inadequate documentation of an event	Data discrepancy
From date:	Initial ICF version: Date signed:	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>	YES* <input type="checkbox"/> NO <input type="checkbox"/>
To date:	Current ICF version: Date signed:	<b>COMMENTS</b> (*Any 'YES' response requires comment):					

HREC Reference for project:	Date of Audit visit:	Tick if there are no items requiring follow-up: <input type="checkbox"/>
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<b>IX. ACTION ITEM SUMMARY</b>				Date of AIS:	Date AIS closed:
#	Issue	Action Required	Responsible	Resolution	Date Resolved
1					
2					
3					
4					
5					
6					