Government of South Australia
SA Health

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PROCEDURE: COMMITTEE REPORTING GUIDELINES

Summary:

This document replaces previous statements from the Royal Adelaide Hospital (RAH) Human Research Ethics Committee (HREC) relating to the information to be provided to the committee in respect of the conduct of Clinical Trials and other Clinical Research which has been approved by the RAH HREC.

The document aligns the requirements of the RAH HREC with those of the NHRMC National Statement on Ethical Conduct in Human Research issued in March 2007 [Ref 1] and NHMRC Australian Health Ethics Committee (AHEC) position statement issued in May 2009.[Ref 2]

The information which follows should be considered to be a minimum requirement and, depending on the complexity, design and risk perceived, the HREC may require that additional information be reported.

TRIAL DOCUMENTATION				
ETHICS COMMITTEE REQUIREMENTS FOR LOCAL REPORTING	**Is reporting required by EC?**	**Does EC acknowledge receipt?**	**Timeframe required by EC for reporting event**	**Additional explanatory information**
Protocol Amendments	Yes	Yes	As soon as possible	All amendments must be submitted. Except for amendments that involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone numbers), the submission documents must include: • A clean and tracked copy of the amended protocol • A summary of changes including the rationale for each amendment
Changes to the PIS/Consent	Yes	Yes	As soon as possible	All amendments must be submitted. The submission documents must include: • A clean and tracked copy of the amended PIS/Consent • An explanation of the need for change
Changes to other trial documentation	Yes	Yes	As soon as possible	Any changes to documents previously approved must be submitted. This may include questionnaires, advertisements, study specific information and instructional information for participants.
Change to Case Report Forms (CRF)	No	No		
Change of Principal Investigator	Yes	Yes	As soon as possible	
Increase of enrolment number at Royal Adelaide Hospital from the originally approved number	Yes	Yes	As soon as possible	

SAFETY RELATED INFORMATION				
ETHICS COMMITTEE REQUIREMENTS FOR LOCAL REPORTING	**Is reporting required by EC?**	**Does EC acknowledge receipt?**	**Timeframe required by EC for reporting event**	**Additional explanatory information**
Serious Adverse Events (SAE) at local site	Yes	Yes	Within 72 hours	Appropriate supporting information such as a copy of the incident documented in a patient's medical record must be provided [Ref 3]
Serious Adverse Device Events (SADE) at local site	Yes	Yes	Within 72 hours	Appropriate supporting information such as a copy of the incident documented in a patient's medical record must be provided.
Unexpected Adverse Device Events (UADE) at local site	Yes	Yes	Within 72 hours	Appropriate supporting information such as a copy of the incident documented in a patient's medical record must be provided.
Adverse Events (AEs)	No	No		Not required unless the occurrence of the AE indicates the need for a change to the trial protocol, including changed safety monitoring
Serious Adverse Events at other sites	Conditional - see comment	Conditional - see comment	Within 72hours	The researcher shall report to the HREC any SAE, irrespective of where it occurred, if it is judged by the researcher or sponsor to materially impact the continued ethical acceptability of the trial or indicates the need for a change to the trial protocol, including changed safety monitoring.
Deviations from informed consent process occurring	Yes	Yes	As soon as possible – within 14 days	
Significant deviations from protocol	Conditional - see comment	Conditional - see comment	Within 72hours	The researcher shall notify the REC of any protocol violation or deviation which is judged by the researcher to materially affect the ongoing safety of the subject in the trial. If protocol exemption granted by the sponsor falls into this category, the event needs to be reported
Other protocol deviations	No	No	With Annual Report	Other protocol deviations which do not meet the above criteria may be reported with the Annual Review.
Patient Withdrawal of Consent	No	No		
Complaints related to study conduct	Yes	Yes	Within 72hours	The researcher shall provide to REC a report on any complaint from participants received by any of the investigators. The report shall contain a description of what occurred and the steps taken to resolve/address the complaint.

PERIODIC REPORTING REQUIREMENTS				
ETHICS COMMITTEE REQUIREMENTS FOR LOCAL REPORTING	**Is reporting required by EC?**	**Does EC acknowledge receipt?**	**Timeframe required by EC for reporting event**	**Additional explanatory information**
Investigator Brochure Update (Sponsored Trials)	Yes	Yes	At least annually	The document must be reviewed and acknowledged by signature of the Investigator. The Investigator must draw to the attention of the committee any information which may impact on ongoing safety of participants in the trial.
Annual Safety Information (Non-Sponsored Trials)	Yes	Yes	At least annually	For trials that are initiated by investigator(s) or a collaborative group of clinicians and in which an IB or PI is unavailable, a trial update may be submitted that provides appropriate review of safety information in the previous 12 months. The document must be reviewed and acknowledged by signature of the Principal Investigator
Suspected unexpected serious adverse reactions (SUSARs) relating to the study drug(s) or devices.	Yes	Yes	At least 6 monthly.	The researcher shall review, interpret and acknowledge, by signature, listings of suspected unexpected serious adverse reactions (SUSARs) relating to the study drug(s). The submission must include the researcher's own opinion in regard to potential impact on ethical acceptability and need for action The listing is provided by the sponsor at least six monthly and should include a statement that indicates action to be taken by the sponsor in relation to the continuation or conduct of the trial.
Study Recruitment closure	No	No		Report in annual review
Changes to the study status.	Yes	Yes	Within 72 hours	If a study is placed on hold or suspended (for example), this must be notified to the committee as soon as possible. An explanation for the change of status must be provided.
Final Study Closure	Yes	Yes	Within 14 days	
Annual Review	Yes	Yes	Annually	From approval date until final study closure
Publications	Optional	No		Submission of publications is optional
Sponsor newsletters or recruitment updates	No	No		

Revision History:

Version 1	4 January 2008	M James
Version 2	25 November 2009	A Thornton
Version 2.1	1 February 2010	A Thornton
Version 2.2		

References:

[1] NHMRC National Statement on Ethical Conduct in Human Research, 2007 Available at: http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf.

[2] NHMRC Australian Health Ethics Committee position statement: Monitoring and reporting of safety for clinical trials involving therapeutic products, May 2009. Available at: http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf

[3] Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - annotated with TGA comments. DSEB. July 2000. http://www.tga.gov.au/docs/html/ich13595.htm)