

CERTIFICATION SCHEME WORKSHEET DESK-TOP ASSESSMENT

CODE: EC00315

Date documentation received: 19/02/2011

Name of institution: Alfred Health

Administering institution? (Y/N) Registered HREC? (Y)

Name of primary contact: s 47F

Telephone of primary contact: 03 9076 5308

Contact date	Details of contact	Actions arising
21/03/11	Acknowledgment of receipt	~~Declaration form not signed~~ Has been received.
16/03/11	Letter arranging on site visit	
24/03/11	Letter confirming on site visit arrangements	
21/03/11	Verification of contact details	
21/03/11	Verification of categories of research	

Categories of Research

Category of research	Number of reviews	Nominated for assessment ☒
Clinical trials of drugs and devices Phase I	51	√
Clinical trials of drugs and devices Phase II	63	√
Clinical trials of drugs and devices Phase III	83	√
Clinical trials of drugs and devices Phase IV	21	√
Population health and/or public health	44	√
Paediatric		
Justice health	2	√
Clinical interventional other than clinical trials	23	√
Qualitative health research	245	√
Mental health	50	√

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Checklist of mandatory documents

Name of document	Reference in SAF	Attachment Number	Received ☒
Self Assessment Form			√
Declaration Form & Checklist			√
Nomination Form			√
HREC Terms of Reference	1.1.7	5 http://www.alfredresearch.org/ethics/committees.htm	√
HREC Conflict of Interest (CoI) declaration(s)	1.1.9	7 – observer, 8 member – no evidence of members having to sign a document declaring COI	√
Policy on managing Conflicts of Interest	1.4.4	6 http://www.alfredresearch.org/ethics/ecguidelines.htm	√
SoP for ethical review	1.5.4	19	√
SoP for administering paperwork for ethical review	1.9.5	19	√
SoP for managing CoI relative to ethical review	1.9.5	17 (page 7), 26	√
Policy on withdrawal of ethical approval	1.10.10	29	√
Letter template informing withdrawal of ethical approval	1.10.10	31	√
Letter template reinstating ethical approval	1.10.10	30	√
Letter template of suspension of research	1.10.10	31	√
Policy on managing serious adverse events, serious drug reactions, serious unexpected adverse reactions and serious adverse device events	1.10.16	35, 38	√
HREC procedure for monitoring clinical research	1.10.16	34	√
Example letter from researcher to HREC regarding serious adverse events, serious drug reactions, serious unexpected adverse reactions and serious adverse device events	1.10.16		x
Letter template informing researcher of necessary actions regarding serious adverse events, serious drug	1.10.16		x

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Name of document	Reference in SAF	Attachment Number	Received ☒
reactions, serious unexpected adverse reactions and serious adverse device events			
Procedure for tracking participants in trials of implantable medical devices	1.10.16		x
Letter template to TGA on device incidents	1.10.16		x

Additional documentation tabled

Name of document
1. Att 1 - Fees for HREC review
2. Att 2 - Organisational Chart
3. Att 3 - Position Description Ethics Officer A
4. Att 4 - Position Description Ethics Officer B
5. Att 8 - Statement and Declaration of Interest
6. Att 9 - Ethics Committee Induction Information
7. Att 10 - Responsible Conduct of Research Policy
8. Att 11 – Membership of Alfred Ethics Committee
9. Att 12 – sample letter to external review expert
10. Att 13 – Lay person ad newspaper Dec 09
11. Att 14 – position description lawyer
12. Att 15 – Appointment new members template
13. Att 16 0 Obligations of Ethics Committee Members
14. Att 18 - Financial code of practice for Alfred Health
15. Att 20 – Instructions for submitting research applications
16. Att 21 – Agreement for the conduct of expert review of a clinical trial
17. Att 22 – Approval Certificate
18. At 23 – Requesting changes to project
19. Att 24 – Sop record keeping and archiving of ethics office files

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20.	Att 25 – Reviewing instructions CD1
21.	Att 27 – Ethics Progress Report Form
22.	Att 28 – Low risk final report
23.	Att 30 – lifting of suspension
24.	Att 32 – Ethics Comm Update Adverse Events Feb 2008
25.	Att 33 – SAE Report Form
26.	Att 35 – Protocol deviations violations guidelines
27.	Att 36 – Initial instructions to researcher
28.	Att 37 – HREC Statement of Indemnity

GROUP ONE: ASSESSMENT CRITERIA BASED ON NATIONAL STATEMENT

Reference	Question	(Y/N)	Action at on site visit
1.1.1/1.1.2/ 1.1.3	Does the response to 1.1.1, 1.1.2 and 1.1.3 demonstrate a reasonable level of institutional resourcing/commitment?	Y	7 administrative staff provides support of ethical review processes. 6 support communication with researchers. - Mix of full time and part time staff.
1.1.6	Does the institution have a policy on fee charging for ethical review?	Y	- The policy provided seems to be an informal document that mirrors what is on their website. - Query if a formalised fee policy has been developed and approved by HoI.
1.1.7	Does the HREC ToR meet requirements under the National Statement 5.1.27?	Y	Query how relationship with non-affiliated researcher would occur if certified.
1.1.11	What does the response say about the relationship between the HREC and the institution?		- HREC is accountable to the institution. - Institution provides indemnity & insurance of members.
	Does the response describe how the HREC workload is managed (e.g. number of applications constituting a 'full' agenda)?	N	- The documentation provided is vague and provides little insight on the day to day operations of the HREC. - Need to determine if the institution has a document that details things like distribution of agenda and papers, what constitutes a full agenda etc.



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Reference	Question	(Y/N)	Action at on site visit
1.2.2	Does the membership composition of the HREC meet requirements of the National Statement 5.1.29?	Y	CV's to be viewed at on-site visit.
1.2.3/1.2.4/ 1.2.5/1.2.6	Has the institution provided evidence of its satisfaction that the background/experience of lay persons, pastoral care and lawyer meet the requirements of the National Statement 5.1.30?	Y	CV's to be viewed at on-site visit.
1.2.3/1.2.4/ 1.2.5/1.2.6	Has the institution provided satisfactory evidence of the independence/degree of affiliation of the lay persons, pastoral care and lawyer to the institution?	Y	To be confirmed at on-site visit.
1.2.8	Does at least one HREC member (including inducted members) have > 1 year HREC experience or hold appropriate academic qualifications?	Y	- HREC – 24/30 members, Research Review Subcommittee – 13/13 members, General Ethics Issues Sub-committee 15/17 members. - Check CV's to confirm
1.2.9	Is the mechanism by which the institution determines 'specialist expertise' transparent? (Is the publication record used?)	Y	- Use VMIA's guidelines - Check CV's of expert reviewers
	Are the individuals utilised by the institution as having 'specialist expertise' relevant to the categories of research nominated by the institution?	Y	Check CV's
1.3.1	Is the mechanism of HREC appointment 'open and transparent'?	Y	Positions are advertised in local and state wide media. Selected applicants are interviewed and appointed on merit.
1.3.2 (link	Have all members received a letter of	Y	Confirm that all current members have received appointment letters.

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Reference	Question	(Y/N)	Action at on site visit
to 7.1.3)	appointment and does that letter indicate how they are legally protected?		
1.4.2	Does the number of days allocated for paper distribution prior to a meeting provide members with sufficient time to prepare?	Y	- Members are provided with papers 21 days prior to a meeting. <i>Not referenced in policy</i>
1.4.4	Does the institutional policy on CoI state which persons are covered by the policy and/or define what is an 'interest'?	Y	Not enough information is given relating to non-monetary conflicts of interest and how they should be dealt with.
1.4.4 (linked to 1.9)	Does the policy include both disclosure of CoI and the management of CoI?	N	- Policy dates back to August 2007 – consider revision. - Insufficient documentation on processes for disclosure and management of CoIs.
1.5.1	Does the institution use SoPs developed/required by jurisdictions or locally developed/ customised SoPs?		- Locally developed – only SOPs for administering ethical review, record keeping and conflicts of interest have been tabled. - Does the HREC have SOPs that cover other areas?
	If SoPs are under development, has the institution nominated a date for completion?		N/A -
1.5.5	Has the institution made it clear whose responsibility it is for promoting the National Statement?	Y	- Numerous links on website. Appointment letters refer to NS. - Does the institution have formal methods of ensuring that members are aware of the requirements of the NS?
1.5.8	Has the institution provided any documentation regarding researcher attendance at meetings?	N	- Response - Phase I researchers are required to attend ethics committee meeting. - Confirm if there is a document that reflects this.
1.5.9	Does the institution use an alternative mechanism to confidentiality agreements to	N	- Researchers are not required to sign confidentiality agreement. - Experts and observers are required to sign confidentiality agreements.

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Reference	Question	(Y/N)	Action at on site visit
	satisfy National Statement 5.2.19?		• Check member files for agreements. • Check minutes for declarations.
1.5.11	If the institution has a policy regarding communication with the HREC, does it satisfy National Statement 5.2.20? If no policy, is there evidence of what is the institutional practice?		• HREC prefers to correspond with researchers who will liaise with sponsors. • Development of an institutional policy detailing practices.
1.6	Has the institution provided example documentation on HREC communication with researchers?	Y	See ToRs, Att 31
1.6.4	Does the tabled documentation provide reasons for the HREC decisions that are clearly linked to the relevant parts of the National Statement?	N	Templates provided however, the response indicates that it is used. Sight letters to researchers at on-site visit.
1.7	Is it clear how the SOP for administering paperwork related to the ethical review aligning with the institutional SOP on record keeping?	N	Detail in documents is vague
1.7.11	Does the public notice indicate a limit to the number of applications that will be considered at each meeting (e.g. full agenda)?	N	http://www.alfredresearch.org/ethics/submisdate.htm • Confirm what constitutes a full agenda. • Note reference on web page: “Any researcher wishing to submit an application for review at this meeting will need to: • Submit a full electronic version of their application • Justify why their application should be accepted for review at this meeting • Agree to pay \$300 for assessment of their justification and application (there will be no refund, even if the application is disallowed)

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Reference	Question	(Y/N)	Action at on site visit
			Be available for interview at the meeting if required. The meeting will begin at 4pm."
1.7.15	Does the institution's process satisfy the intent of National Statement 5.2.30?	Y	Members are required to submit comments prior to the meeting.
1.7.16	Has the institution described its approach to how decisions are reached?	Y	Decisions are reached by consensus the majority of the time however members have voted on decisions if no clear decision was able to be reached by consensus.
	Is this descriptor consistent with the HREC SoP?	N	- No SOP or policy on how decisions are made. - Check if the institution has a documented process for reaching decisions.
1.8.3	Is any role given to the institutional HREC in the governance of research evidenced by the 'necessity' for this role to be undertaken?	?	- Unclear – the HREC has adopted the Consultative Council for Human Research Ethics SOPs however the SOPs relate to clinical trials only. - Institution needs SOPs that reflect all nominated categories of research. - Reference in the SOPs is also made to local policy and there is no evidence of a local policy for this institution.
1.9.3	Has the institution declared they have never needed to implement their policy?	N	Detailed discussion on CoI
1.10	Has the institution provided documentation on its arrangements for monitoring?	Y	Att 34 – Reports are required annually but can be requested more frequently.
1.10.11	What does the response say about the relationship between the institution, the sponsor and the HREC in relation to the management of exception reports?		- Policy pending – when do they expect it will be finalised (Ethics Committee update Feb 2008)? - Confirm how exception reports are managed.
1.10.16	Has the institution/HREC considered the role of the HREC in managing exception reporting for approved inter jurisdictional clinical research?	?	Confirm inter-jurisdictional considerations at on-site visit

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GROUP TWO: ASSESSMENT CRITERIA LINKED TO ARRANGEMENTS FOR THE CONDUCT OF ETHICAL REVIEW

Reference	Question	(Y/N)	Action at on site visit
2.2.2	Has the institution/HREC considered the role of the HREC in incorporating legislative and administrative requirements for approved inter jurisdictional clinical research?	Y	They would seek advice from lawyer who is a member of the HREC.
2.3.2 (linked to 1.1.10/ 3.1.1/3.1.2)	Has the institution adopted a structured approach to succession planning?	Y	- Relevant programs are advertised and members are encouraged to attend. - New members receive and induction and are provided with copies of the NS, the Code and an internal induction information document.

GROUP THREE: ASSESSMENT CRITERIA LINKED TO TRAINING OF HREC MEMBERS AND INSTITUTIONAL ADMINISTRATIVE HREC SUPPORT STAFF

Reference	Question	(Y/N)	Action at on site visit
			View training attendance record – if there is one available

GROUP FOUR: ASSESSMENT CRITERIA LINKED TO INSTITUTIONAL ETHICAL REVIEW PROCESSES OF MULTI-CENTRE RESEARCH

Reference	Question	(Y/N)	Action at on site visit
4.1.1 (linked to 1.2.9)	Has the institution provided a mechanism for all categories nominated for assessment?	Y	View subcommittee CVs at on-site visit.
4.2.1	Does the response indicate what action the institution takes in the event that the protocol is not followed?		

note - that documentation provided supports processes for clinical trials, not other categories

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GROUP FIVE: ASSESSMENT CRITERIA LINKED TO ETHICAL REVIEW OF MULTI-CENTRE CLINICAL TRIALS PROPOSALS OR MULTI-CENTRE CLINICAL INTERVENTIONAL RESEARCH PROPOSALS

Reference	Question	(Y/N)	Action at on site visit
5.2.1 (linked to 2.2)	Does the response indicate what legislative frameworks the institution views as relevant?	Y	Confirm understanding of other legislative requirements at on-site visit.

GROUP SIX: ASSESSMENT CRITERIA LINKED TO INSTITUTIONAL POLICY AND ADMINISTRATIVE PROCESSES SUPPORTING ETHICAL REVIEW

Reference	Question	(Y/N)	Action at on site visit
6.1.1/ 6.1.3 (linked to 1.1.1)	Does the response consider how HREC workload may change in relation to obtaining certification of ethical review processes?	Y	Extra meetings will be convened, if necessary and consideration would be given to recruitment of additional support staff.
6.3.1	Does the response indicate what national processes and procedures are to be adopted?	Y	
6.3.2	Does the institution already use NEAF?	Y	
6.4 (linked to 4.2.1)	Does the response indicate what action the institution takes in the event that the protocol is not followed?	N	

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GROUP SEVEN: ASSESSMENT CRITERIA LINKED TO INSTITUTIONAL COMMITMENT

Reference	Question	(Y/N)	Action at on site visit
7.1.2	If there are criteria, is this publicly available?	N	- No criteria established. - Have they considered developing a document detailing criteria for multi-centre ethical review.
7.2.1 (linked to 1.5)	Is the response consistent with the response to 1.5?	N	7.2.1 states that the policy is under development – expected mid 2011
7.3.1 (linked to 1.1)	Does the response indicate how the institution determined support was sufficient?	Y	Seven administrative staff with a view to increasing if the need arises – see group 6 criteria.

Website: <http://www.alfredresearch.org/index.htm>

Evidence suggests that the HREC has significant experience however evidence of the documentation of processes is minimal.

