Appendix 1: Review of BETA Research Management vs National Statement Requirements

NS Ref	National Statement Obligation	BETA Position	Recommended Action
	Research Governance		
5.1.1	Institutions must see that any human research they conduct of for which they are responsible is:		
	(a) designed and conducted in accordance with the Australian Code for the responsible conduct of research, and	BETA has a team of specialist staff with a variety of appropriate backgrounds. Within the team they have specialist research expertise.	Ensure staff are appropriately trained in the development of evaluation research and the National Statement. Consider including this as part of the induction process for new staff with refresher training at appropriate intervals. Ensure that staff from a non-research background receive appropriate training or support. Consider including the Australian Code in required reading as part of the induction process.
	(b) ethically reviewed and monitored in accordance with this National Statement	BETA has a documented process for determining the risk level of research and appropriate mechanisms (both HREC and non-HREC) for ethical review.	BETA should consider the recommended updates to their research management processes and policies arising from the review.
5.1.2	Each institution needs to be satisfied that:		
	(a) its human research meets relevant scholarly or scientific standards;	BETA has initiated this review, and is well aware, and committed to the appropriate standards.	N/A
	(b) those conducting its human research:		
	(i) are either adequately experienced and qualified, or supervised;	BETA have appointed research-qualified and -experienced staff to senior roles. BETA team members are partnering with team members in other Departments, and can provide appropriate supervision as required.	Consider the need for awareness training in partner Departments and agencies.
	(ii) understand the need to assess risks to their own safety and that of participants; and	The BETA team demonstrated good awareness of risks as might exist for both researcher and participant. However, the nuance often associated with risk assessment and categorisation is not currently documented in the process documentation.	Ensure research and ethics training covers risks as they apply to both researcher and research participants. Our recommendation is to ensure that training includes pragmatic scenarios to contextualise risk in the settings in which BETA are most likely to find themselves. Ensure Research Management Policy articulates the intended approach to both risk and risk minimisation. Ensure evauation protocols articulate the approach to be taken relevant to the project.
	(iii) are free to withdraw from research on conscientious grounds.	No evidence of policy.	Update the BETA Project Management Toolkit to reflect both escalation and withdrawal processes.
5.1.3	Institutions may establish their own processes for ethical review of research, or use those of another institution.	BETA has established alternative review mechanisms, both their own and using external HRECs. Research Management Policy articulates the use of alternative mechanisms of review.	Update policy documentation to reflect the use of the Ethics Delegate.
5.1.4	Whichever option under 5.1.3 is adopted, institutions need to be satisfied that processes are in place for:		
	(a) managing conflicts of interest (Chapter 5.4);	No documented policy at present.	Research Management Policy statement should include a statement of intent against each of these points.
	(b) monitoring research (Chapter 5.5);		
	(c) handling complaints (Chapter 5.6); and		
	(d) ensuring accountability (Chapter 5.7).		
5.1.5	Institutions should use and promote clearly formulated, documented, accessible and current policies and procedures for research governance and ethical review.	BETA has established alternative review mechanisms, both their own and using external HRECs. Research Management Policy articulates the use of alternative mechanisms of review.	N/A
5.1.6	**Processes for ethical review**		
	The following types of research require review by a Human Research Ethics Committee (HREC):		
	(a) all research that involves more than low risk;	The BETA process allows for both review by a partner organisation HREC or an external independent HREC.	The bar for "research that involved more than low risk" has been set at a low level in the Australian regulations. Low risk is defined as research where the "only forseeable risk is discomfort", whereas "more than low risk" is defined as "any research where risks involve more than simply discomfort". Discomfort can be considered in terms of general inconvenience; physical discomfort; impacts on mental health; or emotional distress. Bellberry would recommend that BETA develop model illustrations contextualising risk levels and possible participant impacts in order to help develop research classifications. A draft example has been provided in the Risk Spectrum document. For research that is more than low risk (under the BETA research classification process), BETA should initiate an HREC review according to the National Statement. This process should be articulated in the Research Management Policy.
	(b) research falling under the following chapters (except where research on collections of non-identifiable data under these chapters satisfies the conditions for exemption from review – see paragraphs 5.1.22 and 5.1.23): Chapter 2.3.9: waivers of consent for "research using personal information in medical research, or personal health information"; Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations Chapter 3.5: Human genetics, Chapter 4.1: Women who are pregnant and the human fetus, Chapter 4.4: People highly dependent on medical care who may be unable to give consent, Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness, Chapter 4.7: Aboriginal and Torres Strait Islander Peoples, and some categories of research falling under Chapter 4.6: People who may be involved in illegal activities (see first bolded paragraph for details).	BETA Risk Assessment 2 (continued) is directed at understanding the involvement of special groups as identified under National Statement 5.1.6(b).	Consider the need for an additional "other" category to capture other groups exhibiting vulnerability (eg domestic violence abuse victims, families affected by historical trauma, etc).
5.1.7	For research that carries only low risk (see paragraph 2.1.6) and does not fall under any of the chapters listed in paragraph 5.1.6, institutions may choose to establish other levels of ethical review. These levels are described in paragraphs 5.1.18 to 5.1.21.	BETA has an internal Committee of Peers process for Low Risk research. This Committee has a documented Terms of Reference, and will be Chaired by the Ethics Delegate.	Bellberry would like to review the meeting documentation for the Committee of Peers process, and the record of outcomes of such discussions. Bellberry would recommend escalation processes be determined.
5.1.8	Research that carries only negligible risk (see paragraph 2.1.7) and meets the requirements of paragraphs 5.1.22 and 5.1.23 may be exempted from ethical review.	Under the BETA policy, a negligible risk research project will be evaluated only by the Project Manager using the Policy and Process. All completed Risk Assessments will be reviewed and approved by the Ethics Delegate.	Bellberry seeks clarification about process in cases where the Ethics Delegate disagrees with the decision of the Project Manager to categorise research as either negligible or low risk. The Ethics Delegate will have the final decision in these cases.
5.1.9	**Legal protection for those involved in ethical review of research**		
	Institutions should provide an assurance of legal protection to all those involved in ethical review of research, for liabilities that may arise in the course of bona fide conduct of their duties in this capacity	No information yet provided.	BETA should provide legal protection to all involved in the processes described. This may be by insurance and/or indemnity.
5.1.10	**Oversight and review of ethical review procedures**		
	Institutions that set up levels of ethical review other than HREC, as described in paragraphs 5.1.18 to 5.1.23, must establish criteria for allocating research to these different levels of review (including exemption from review), taking into account Chapter 2.1: Risk and benefit. These criteria must be readily accessible to all those involved in the conduct and review of research.	BETA has established alternative review mechanisms, both their own and using external HRECs. The Research Management Policy does not currently articulate oversight and review of review processes. These are required for non-HREC reviews.	BETA is required to provide oversight processes for research reviews not undertaken by HREC. This may be a regular portfolio review. Bellberry can assist with agenda development if needed. BETA is required to provide review of review processes for both project manager assessment and Committee of Peer assessments.
5.1.11	The ethical values and principles in this National Statement should be the basis on which institutions establish different levels of ethical review, allocate different kinds of research to them, and review those allocations.	BETA policy and processes refer to the National Statement requirements.	Bellberry can assist with suggestions if required.
5.1.12	Institutions must monitor any processes of ethical review of low risk research to ensure those processes continue to provide sufficient protection for participants.	The Research Management Policy does not currently articulate a process for the monitoring of the effectiveness of review processes.	An annual review should be conducted. This review should: - Review the Research Management Policy and update as necessary; - Review the risk classification descriptions and the review pathway and update as necessary for any company changes; - Review the annual summary of Low and Negligable Risk projects reviewed to confirm that these were appropriately classified and handled. In due course, it may be appropriate to lengthen the time between reviews from 1 to 2 or even 3 years. The interval should be decided based on the stability of the type of research undertaken and the pace of change in external factors.
5.1.13	Institutions should regularly assess all their ethical review processes, including the criteria for allocating research to different levels of review, to ensure that those processes continue to enable the institution to meet its responsibilities under this National Statement.	The January 2018 review provides an assessment of BETA processes relating to the National Statement.	
5.1.14	Where possible this assessment should be informed by the documented experience of research participants and/ or by involving participants or the wider community in the assessment.	Not currently in place.	
5.1.15	Institutions should also remain alert to emerging ethical issues in any area of human research that may warrant changing the level of ethical review required.	Not currently in place.	
5.1.16	To enable assessment of their ethical review processes, institutions should prepare and make readily accessible regular reports on all of those processes.	Not currently in place.	BETA should keep a record of reviews conducted (both through any defined internal pathway, and through Certified HRECs) to be used in the annual reserch review. BETA should consider making summary information available.
5.1.17	Institutions should have in place an auditing process to confirm that:		
	(a) research in their institution is being reviewed at the levels of review their criteria require;	BETA has appointed an Ethics Delegate to provide this oversight.	The Ethics Delegate will have the right to overturn a decision made to use a Project Manager or Committee of Peers assessment.
	(b) research is being exempted from review only in accordance with the criteria set out in paragraphs 5.1.22 and 5.1.23.	BETA has appointed an Ethics Delegate to provide this oversight.	
5.1.18	**Research involving no more than low risk**		
	Institutions that establish any non-HREC levels of ethical review for low risk research must have the resources and capacity to carry out such review competently and professionally.	Capacity to undertake this was not explored during the site review. BETA have contracted for specialist ethics support for an initial period.	BETA should determine the organisational capacity to meet this requirement. The alternative is to outsource to an HREC, with associated costs. In the capacity and cost determination, it is important to factor in the competence of the available internal resource, along with any further investment required, for example in training needs.
5.1.19	Where institutions establish such non-HREC levels of ethical review for low risk research, that review must:		
	(a) be carried out by people who are familiar with this National Statement and have an understanding of the ethical issues that can arise in the research under review;	All BETA Project Managers must undertake National Statement training to ensure they meet this requirement when making decisions about the risk caetgorisation of research.	As the BETA processes are built on the foundation of Project Managers undertaking BETA reviews, it is important that all Project Managers have appropriate awareness and understanding of the National Statement. Induction training is recommended. The BETA process must be udpated to reflect the importance of the researcher view about the appropriateness of review. BETA Project Teams should have current Privacy awareness training, noting in particular that many of the projects undertaken will involve large data sets, and largely with waiver of consent, or under secondary use frameworks.
	(b) be informed by Section 1: Values and Principles of Ethical Conduct, Section 3: Ethical Considerations Specific to Research Methods or Fields and Section 4: Ethical Considerations Specific to Participants;	All BETA Project Managers must undertake National Statement training to ensure they meet this requirement when making decisions about the risk caetgorisation of research.	
	(c) take account of researchers' judgements as to whether their research is suitable for review by a non-HREC process;	Not currently in place.	
	(d) have due regard to relevant privacy regulation.	Not currently in place.	

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5.1.20	The levels of ethical review referred to in paragraph 5.1.18 may include, but need not be limited to:		
	(a) review or assessment at departmental level by the head of department;	The BETA framework involves alternative review processes utilising Project Managers, a Committee of Peers, the support of an expert Ethics Delegate, and full HREC review by external HRECs.	N/A
	(b) review or assessment by a departmental committee of peers (with or without external or independent members);		
	(c) delegated review with reporting to an HREC; or		
	(d) review by a subcommittee of an HREC.		
5.1.21	Those reviewing research at a non-HREC level must refer to an HREC any research they identify as involving more than low risk.	Not currently articulated in the Procedure.	The Research Management Policy should articulate an escalation process and pathway to be used if it is determined that a full HREC review is required.
	Research that can be exempted from review		
5.1.22	Institutions may choose to exempt from ethical review research that:		
	(a) is negligible risk research (as defined in paragraph 2.1.7); and	Risk categorisation makes this distinction.	N/A
	(b) involves the use of existing collections of data or records that contain only non-identifiable data about human beings.		
5.1.23	Institutions must recognise that in deciding to exempt research from ethical review, they are determining that the research meets the requirements of this National Statement and is ethically acceptable.	This Risk Classification is used.	In this situation BETA is taking the responsibility for determining ethical acceptability.
	HRECs: research involving more than low risk		
5.1.24	Each institution that conducts human research involving more than low risk must ensure that this research is reviewed and approved by an HREC that is constituted and functioning in accordance with this National Statement, whether or not that HREC is established by the institution.	BETA has processes in place for risk categorisation and use of appropriate review mechanisms.	Bellberry would strongly advise against BETA establishing an internal HREC for a number of reasons. Most important of these is that HRECs require a minimum workload in order to maintain competence, and this unlikely to be achievable for a single company. Other reasons include capability, independence, conflict of interest, and cost.
5.1.25	Institutions that establish HRECs are responsible for ensuring that those HRECs are established and continue to operate in accordance with this National Statement.	Not currently relevant.	Bellberry would strongly advise against the establishment of an internal HREC. We would advise the use of an NHMRC-Certified HREC, whether a Bellberry HREC or other.
5.1.26	**Establishment of HRECs**		
	Institutions that individually or jointly establish HRECs should adequately resource and maintain them. Resourcing should be sufficient to enable HRECs:	Not currently relevant.	Use of an NHMRC-Certified Committee ensures compliance with the National Statement.
	(a) to satisfy the requirements for sound ethical review (see paragraph 5.1.37);		
	(b) to communicate well with researchers (see paragraphs 5.2.13 to 5.2.15);		
	(c) not to charge fees where doing so would discourage research the institution has an obligation to support.		
5.1.27	When establishing an HREC, an institution should set out and publicise its terms of reference, including:		
	(a) the scope of its responsibilities for ethical review;		
	(b) its relationship to other processes of research review;		
	(c) its relationship to non-affiliated researchers;		
	(d) its institutional accountability		
	(e) its mechanisms of reporting;		
	(f) categories of minimum membership; and		
	(g) remuneration, if any, for members.		
5.1.28	Where an institution has established an HREC, the institution is responsible for ensuring that:		
	(a) members have relevant experience and/or expertise;	Not relevant as external HRECs have been nominated for use.	Use of an NHMRC-Certified Committee ensures compliance with the National Statement.
	(b) members undertake:		
	(i) appropriate induction, which could include mentoring by a current HREC member, and		
	(ii) continuing education;		
	(c) review of research proposals is thorough;		
	(d) review processes and procedures are expeditious;		
	(e) decisions are transparent, consistent, and promptly communicated;		
	(f) actual and potential conflicts of interest that may affect research and its review are identified and managed (see Chapter 5.4: Conflicts of interest);		
	(g) membership of the HREC is made public in annual reports or by other routine processes, and is available to researchers submitting research proposals to that HREC;		
	(h) good communication between the institution/s, the HREC and researchers is promoted;		
	(i) the workload of the HREC does not compromise the quality and timeliness of ethical review; and		
	(j) any institution using the HREC can be assured the HREC is operating in accordance with this National Statement.		
5.1.29	**Composition of HRECs**		
	The minimum membership of an HREC is eight. As far as possible: (a) there should be equal numbers of men and women; and (b) at least one third of the members should be from outside the institution for which the HREC is reviewing research.	Not relevant as external HRECs have been nominated for use.	Use of an NHMRC-Certified Committee ensures compliance with the National Statement. A benefit of the Bellberry HREC process that is significantly different to other traditional committees, is that Bellberry HREC membership is tailored on a meeting-by-meeting basis to ensure that the most appropriate skills are appointed to the review of research. This feature aims to provide the most relevant review to the researcher.
5.1.30	This minimum membership is:		
	(a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;		
	(b) at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;		
	(c) at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;		
	(d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;		
	(e) at least one lawyer, where possible one who is not engaged to advise the institution; and		
	(f) at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.		
5.1.31	No member may be appointed in more than one of the categories listed in paragraph 5.1.30, but institutions are encouraged to establish a pool of inducted members in each category. These members may attend meetings as needed to meet minimum HREC requirements, and may also be available to provide expertise for the research under review.		
5.1.32	Wherever possible one or more of the members listed in 5.1.30 should be experienced in reflecting on and analysing ethical decision-making.		
5.1.33	The institution should ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.		
5.1.34	**Appointment of HREC members**		
	Members should be appointed to an HREC using open and transparent processes. Institutions should consider reviewing appointments to the HREC at least every three years.	Not relevant as external HRECs have been nominated for use.	Use of an NHMRC-Certified Committee ensures compliance with the National Statement.
5.1.35	Members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organization, group or opinion.		
5.1.36	Members should be provided with a formal notice of appointment.		
5.1.37	**HREC procedures**		
	An institution that establishes an HREC should ensure that the HREC establishes, implements and documents working procedures to promote good ethical review, including procedures for:		
	(a) frequency of meetings;	Not relevant as external HRECs have been nominated for use.	Use of an NHMRC-Certified Committee ensures compliance with the National Statement.
	(b) attendance at meetings;		
	(c) conduct and structure of meetings and deliberations;		
	(d) preparation of agendas and minutes;		
	(e) timely distribution of papers before meetings;		
	(f) presentation of applications for ethical review;		
	(g) timely consideration and review of applications;		
	(h) managing conflicts of interest (see paragraphs 5.4.1 to 5.4.6);		
	(i) communicating with researchers, including face to face, by telephone and in writing (including email) (see paragraphs 5.2.13 to 5.2.15);		
	(j) reporting on its activities to the institution;		
	(k) methods of decision making;		
	(l) prompt notification of decisions;		
	(m) record keeping (see paragraphs 5.2.23 to 5.2.27);		
	(n) monitoring of approved research (see paragraphs 5.5.1 to 5.5.5);		
	(o) reporting and handling of adverse events;		
	(p) receiving and handling of complaints (see paragraphs 5.6.1 to 5.6.7);		
	(q) advising the institution/s of decisions to withdraw ethical approval of a research project (see paragraphs 5.5.7 to 5.5.9);		
	(r) attendance, as observers, of people other than members or researchers (see paragraph 5.2.18) at meetings;		
	(s) fees, if any, to be charged; and		
	(t) appropriate confidentiality of the content of applications and the deliberations of review bodies.		