BETA RESEARCH ETHICS PROCESS REVIEW

January 2018

Abstract

Bellberry undertook a review of BETA Research Ethics Policies and Processes in January 2018. This report summarises the key findings, with recommendations for improvement.

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supporting research and ethics

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2. Executive Summary

The BETA team undertakes projects and supports initiatives across a range of government departments. These projects aim to use the principles of behavioural economics to develop more effective policies and interventions. BETA aims to run comparative trials in order to assess the effectiveness of proposed interventions and policies in order to better inform final policy decisions.

The BETA team has established a set of research ethics governance policies and processes to articulate the ways in which it will handle these projects and the trials of interventions.

The BETA process identifies a range of research ethics review mechanisms, from internal project manager-led reviews, to departmental peer review, to a full HREC review. The use of a variety of review mechanisms is supported by the National Statement.

The policies and procedures include a decision tree to assist with the assessment of the level of risk associated with each project, and identify which review mechanism is to be used.

Bellberry has been contracted to provide Ethics Delegate support, and access to an independent HREC pathway where appropriate

In January 2018, a review of policies relating to the management of research and processes determining research review was undertaken by Bellberry, the largest provider of Human Research Ethics review in Australia. Bellberry also undertook a collaborative workshop in January 2018 with members of the BETA research team.

The staff members of the BETA team have a high level of awareness of the general requirements of Research Ethics, and a strong commitment to operate within recommended boundaries. The BETA team have good and documented evidence to demonstrate the institutional approach for ensuring compliance with Australian Research Ethics regulations including the National Statement.

Bellberry has identified some gaps in the existing policy and procedural framework, and has provided a recommendation about actions to be taken. In addition, Bellberry has provided a risk assessment guidance tool (the Risk Spectrum), which was developed in collaboration with the BETA team. We recommend that the risk spectrum tool is added to the policy manual. The body of work required to update the policies and processes has been outlined in the Review Findings table at section 4. It is anticipated that the programme of work could reasonably be completed within a 1-2-month timeframe using mainly internal resources.

3. Review Process

The review process was conducted over a number of stages:

1. *Pre-work and desk-based review*

Pre-work comprised of a desktop review of documentation provided by BETA relating to the BETA Project Management Toolkit, Terms of Reference, and Risk Assessment processes. In addition, a list of current BETA projects was provided.

2. *Overview of Australian Research Ethics Requirements*

The workshop was presented using the National Statement on Ethical Conduct in Human Research 2007 (the National Statement) as a framework. Particular emphasis was given to Institutional obligations, as laid out in the National Statement. Focus was also given to the mechanisms which allow demonstration of compliance with these obligations, along with associated and additional requirements.

Bellberry presented a Research Ethics Review Framework (developed from the National Statement), and the existing BETA requirements were mapped to this framework.

3. *Discussion-based review of BETA processes*

A collaborative approach was used during the workshop to compare the National Statement requirements with the existing BETA policies and procedures. This review was undertaken in key topic areas: types of research activities, risks and review mechanisms. The output from these discussions was used to develop the risk assessment guidance tool ("the Risk Spectrum"), and to populate the Review Framework.

4. *Research Ethics Clinic*

To complete the workshop, a question and answer session was held in order to explore issues currently facing BETA project teams in relation to Research Ethics, Design and Research Conduct.

4. Review Agenda

Scope of discussion:	Research, ethics and governance review. Discovery phase investigation. Review work to understand type of research undertaken by the organisation. Review existing governance practices, including policies and SOPs. Provide output report including recommendations for improvement.
Information Required from BETA prior to workshop:	- Relevant Governance Documentation. - Policies and SOPs related to research and evaluation workload.
Bellberry team:	Kylie Sproston, CEO. Trina O'Donnell, Operations Manager. Prof Paula Swatman, nominated Ethics Delegate.
BETA attendees:	To be completed by BETA

5. Review Findings & Recommendations

Topic	Content	Findings & Recommendations

Research Governance	Overview of Research Ethics Governance processes:
	- Project Management Toolkit
	- List of Current BETA Projects
	- BETA Ethical Risk Assessment Form
	- BETA Ethical Risk Identification and Management Process Flowchart
	- BETA Ethical Committee of Peers Application Form
	- BETA Ethics Committee of Peers
	- Data Usage and Security Background Brief
		BETA has an existing and documented Research Project Management Policy and a supporting SOP regarding research risk assessment.
		The BETA documents provide structured questions derived from the National Statement which help the project manager to determine if the project includes any direct triggers for specialist review (for example vulnerable participants) and consider the areas of risk associated with each project.
		The BETA documents also provide a range of review mechanisms for a variety of risk levels. These mechanisms range from Project Manager assessment to Committee of Peer Review to full HREC review.
		The BETA documents also include a flowchart describing the Ethical Management Processes, and a decision pathway. The risk assessment is structured in 4 sections:
		- Assessment Part 1: Level of Risk (Negligible, Low, Greater than Low)
		- Assessment Part 2: Exemption from Ethical Risk (Negligible risk with no foreseeable harm or discomfort)
		- Assessment Part 2 continued: Special populations requiring HREC review
		- Assessment Part 3:
		  ○ Data collection and privacy
		  ○ Sensitive topics and groups
		  ○ Research methodology
		  ○ Other risks
		
		It is our view the process flowchart does not reflect all of the questions in the assessment parts (1, 2 & 3) or all of the available pathways, escalation pathways, and risk recategorization as a result of “yes” answers at Part 3. To be clear, if “yes” is answered to any question in Part 3, then greater than low risk is likely.

Topic	Content	Findings & Recommendations
		RECOMMENDATIONS: In our view a few additions are required to the risk assessment form. These suggestions can be seen annotated on the flowchart at Appendix 5. 1. Structure of Risk Assessment Form: At the moment there are 3 risk assessment parts followed by a decision tree. The form reads as if, once a categorisation has been reached, then no further questions need be answered. For example, if no specific groups are noted in section 2(continued), then no further information in section 3 need be given. Section 3 is where nuance about content will be given, and so should be completed in all cases. Furthermore, section 3 answers may lead to a recategorization of the risk level in Part 1. 2. Summary of Decision: It may help to have a summary of decision making table at the end of the document to assist with the decision tree. 3. Assessment Part 1 (page 2): While risks are to be broadly categorised into negligible, low, and greater than low risk research – these are not simple categorisations to make. During the workshop, the team discussed many examples where the same research instrument could be variously categorised as negligible, low and greater than low risk depending on the content and context of the research itself, or by considerations of the research area and participant type. It is therefore our recommendation that more guidance is provided to assist with the determination of various risk types. A draft "risk spectrum" has been developed based on the workshop discussions to assist with this process. 4. Assessment Part 2 continued (page 2-3):

Topic	Content	Findings & Recommendations
		Assessment Part 2 comprises two parts: "Exemption from ethical review" and "Requiring HREC review". These should be labelled separately as they related to separate zones on the decision tree. They could be labelled 2(a) and 2(b), or 2, 3 and 4 for the existing section 3. 5. Requiring HREC review (page 3): Current Part 2(b) lists the specified populations currently listed in the National Statement. Bellberry is of the view that this section of the National Statement describes vulnerable populations, of which some specific groups are defined. However, "vulnerability" should be considered as a standalone question, as there are other vulnerabilities that would also trigger a need for more specialist considerations. This could be added as simply an "other" question seeking guidance about any other form of vulnerability that should be considered. 6. Assessment Part 3 (pages 4-7): Guidance should be given as to how to use the answers to these questions to determine the level of risk. A draft Risk Spectrum has been provided as a suggested process that may be useful. This can be seen at Appendix 6. 7. Assessment Part 3 (page 7): The Part 3 assessment should be updated to reflect the use of the nominated Ethics Delegate. 8. BETA Ethical Risk Identification and Management Process Flowchart (page 9): It is suggested that the flowchart is marked up to provide a connection between the questions and answers given through the Risk Assessment and the pathway to be followed. Suggested changes are shown in Appendix 5. 9. Decision Pathways: Further description is required to the Greater than Low Risk and HREC pathways, as this is often determined by nuance. 10. Escalation Pathways:

Topic	Content	Findings & Recommendations
		The National Statement requires that escalation pathways exist. These escalation pathways should enable research that has been reviewed by an alternate mechanism to an HREC to be escalated to a full HREC review at any time. This provides support for the cases where risks transpire to be greater than first anticipated. It should be made clear that the researcher has the ability at any time to request the escalation of the research to a full HREC. 11. A note on risk determination: It should be noted that where a risk categorisation is a "close call", the conservative approach is to err on the side of caution and categorise upwards in the risk scale rather than down. It can be difficult for an HREC to review research retrospectively without requesting changes that may incur rework.
Consent Considerations	N/A	A variety of structures exist for research consent: - Fully-informed and individual Participant Consent (Opt-in) - Opt-out consent - Implied consent (e.g. submission of a completed survey questionnaire for which no other consent has been provided) - Waiver of consent (Waiver of consent is often mistakenly understood to mean that there is no consent for the research study. It is probably better (though still incorrectly) understood as the HREC providing consent on behalf of research participants.) Only an HREC may grant waiver of consent for research, and before doing so must consider a number of factors as guided by the National Statement. It is anticipated that BETA studies will involve all of these forms of consent processes.

Topic	Content	Findings & Recommendations
		RECOMMENDATIONS: 12. Questions about the consent process to be used should be added to the Risk Assessment form. 13. It is understood that many BETA projects will not use Opt-in Consent processes. Given that BETA has a stated commitment to publish the findings of research (see Project Management Toolkit), and the public-facing nature of many of the projects, it is suggested that a Consent Information document is developed and published that articulates the BETA approach to participant information. This information statement should include elements such as: - the use of appropriate consent structures; - the types of research in which each might be deployed; - HREC involvement in waiver of consent situations; - The use of secondary data; - Situations where no consent is required.
Participant Considerations	N/A	Most research organisations will have standard documentation for participant interactions. These standard documents may include: - Invitation to participate - Participant information pack - Consent form - Withdrawal of consent form - Complaints process Bellberry was not provided with any Participant-related documents for review. *RECOMMENDATIONS:* 14. Given the nature of BETA studies, it is anticipated that individual participants will not be engaged prior to their involvement in the research. In these cases, it would

Topic	Content	Findings & Recommendations
		be considered respectful to provide information on the research once it has been completed. 15. Similarly, it is suggested that the BETA team develop a statement of intent relating to Participants. This statement may include: - Over-riding principles and commitments relating to respectful research practices. - Information regarding project processes, and the intent to publish outcomes. - Given that BETA have a stated commitment to publish outcomes, a one-page summary outcome statement could be a useful document that replaces the prior participant information process. 16. The National Statement requires institutions to have a Complaints process in place. It would be prudent to develop this process ahead of time. For research projects reviewed by Bellberry HREC, Bellberry provides an independent point of contact for participants.
Research Evaluation	N/A	The workshop discussed the "standard process" of: (1) Research Project followed by (2) Evaluation of the Research Project. *RECOMMENDATIONS:* 17. In cases where there is a Research Project and a subsequent evaluation, it is necessary to have very clear delineation between the two phases of work. The evaluation documentation needs to (for example) clearly state that the plan is to "evaluate the project", rather than to "implement and test the intervention". 18. Bellberry strongly recommends that in cases where the project evaluation is considered to need HREC review, then the core project should also be reviewed by the HREC. Ideally, the evaluation overview should be presented at the same time, and as part of the core research review. It is understood that new elements or specific questions may be added to the evaluation through the course of the

Topic	Content	Findings & Recommendations
		research process. This can be dealt with by Amendment without a full and new application being needed. 19. In cases where the core research and any subsequent evaluation cannot be submitted at the same time, then Bellberry will recommend using the same HREC to review the both stages. 20. In cases where the core research has not been submitted for review to any HREC, then Bellberry reserves the right to refuse to provide HREC review for any subsequent evaluation stage alone.
Research Monitoring	List of current BETA Projects	The National Statement requires a process of evaluation of research (which should be noted to be distinct from the "evaluation" activities likely to be included in BETA-type intervention trials). Evaluation in this context should be understood to be a process of annual review of the portfolio of research projects, with an assessment about progress, conduct, and any issues arising. Most HREC-monitored trials do this by submitting an annual progress report. BETA may choose instead to have a regular (e.g. quarterly or annual) portfolio review. Indeed this process may already be in place within BETA – but is likely focussed on project management principles rather than research ethics and governance questions. *RECOMMENDATIONS:* 21. Bellberry recommends that BETA constitutes a regular review process to provide oversight for the portfolio of projects. It is recommended that the Ethics Delegate and/or Bellberry is an invited attendee to that forum. Assistance may be provided for agenda development if needed. 22. Bellberry recommends that BETA establish a system to manage ongoing monitoring requirements (such as progress milestones, annual report due dates, complaints, protocol violations etc).

Topic	Content	Findings & Recommendations
Data Governance	Data Usage and Security Background Brief	Data management is becoming an increasingly complex issue for research at all levels (collection, storage, retention, (re)use, disclosure and ultimate destruction). Changing government privacy requirements and the increased risk/s created by social networks and Big Data (e.g. loss of anonymity, data breaches, ability to connect disparate data sources) add to an HREC's data management responsibilities. The National Statement already requires evaluation of the collection, storage, use and disclosure of data, with a particular focus on consent; and discusses the special problems of formal Data Linkage. More and more, however, data access and linkage is informally obtained via social networks or algorithmic access to formerly inaccessible datasets, requiring researchers and HRECs to identify potential ethical risks affecting the reality of participant consent and risk. *RECOMMENDATIONS:* 23. Bellberry recommends the creation of 'data governance' guidelines which could be used to evaluate and rank the various data and privacy risks involved in individual projects, simplifying ethics application creation and review.
Research Administration	Standard approaches to Project Files	Standardised approaches to research projects and project documentation can assist with the development of robust and consistent research protocols, and thus support the streamlining of both project management and ethical review. *RECOMMENDATIONS:* 24. Bellberry recommends the creation of a BETA standard project file including the main and repeatable elements as templates. Notably this would include (as needed and appropriate): Project Protocol, Participant Information, Evaluation Plan, Data Governance, etc. Assistance can be given with templates if needed.

Topic	Content	Findings & Recommendations
		25. The suite of BETA documents should be subject to a regular review and update process (suggest annual for the first 2 years, moving to every 2 years thereafter).
National Statement Obligations of Institutions	Following the review, BETA research management processes were mapped against the National Statement Institutional obligations. Where gaps were identified, recommended actions have been listed.	A number of actions have been identified and are outlined on the mapping document.

6. Discussion

Australian guidance on the requirements relating to research involving people is enshrined within the National Statement on Ethical Conduct in Human Research 2007 (the National Statement).

The National Statement outlines the responsibilities of all parties involved in research, including the Institution, Sponsor, Researcher, the Human Research Ethics Committee (HREC) and so on. For the work undertaken by BETA you should understand "the Institution" to be BETA, "the Sponsor" to be the commissioning body (which is likely to be either BETA or the partner Department/Agency) and "the Researcher" to be a group of people including research and project management personnel and site-/event-based staff who are undertaking research questions.

The National Statement outlines what researchers and research organisations should do in order to undertake ethical human research in Australia.

BETA processes have been mapped to the detailed National Statement requirements, with clause references, at Appendix 1. This document also contains recommendations for further work.

The summary requirements are shown in the Research Framework shown at Appendix 2. The BETA summary processes as described are captured in Appendix 3.

BETA has established good policy and process documentation articulating the approach to research. A small number of additions to this policy have been suggested. For the main part, these can be added to the existing documentation. More significant actions relate to the development of a small number of additional Statements or Policy documents. Bellberry is able to assist with these if desired. A summary of best practice inclusions a Research Management Policy has been included for information at Appendix 4.

The addition of the external Ethics Delegate should also be articulated in the guidance documentation, along with the availability of the Bellberry helpline for advice and assistance at any stage (whether research is determined to require HREC review or not).

7. Actions

The following actions are recommended. They have been allocated to a time frame to give an indication of a project plan to follow towards National Statement compliance.

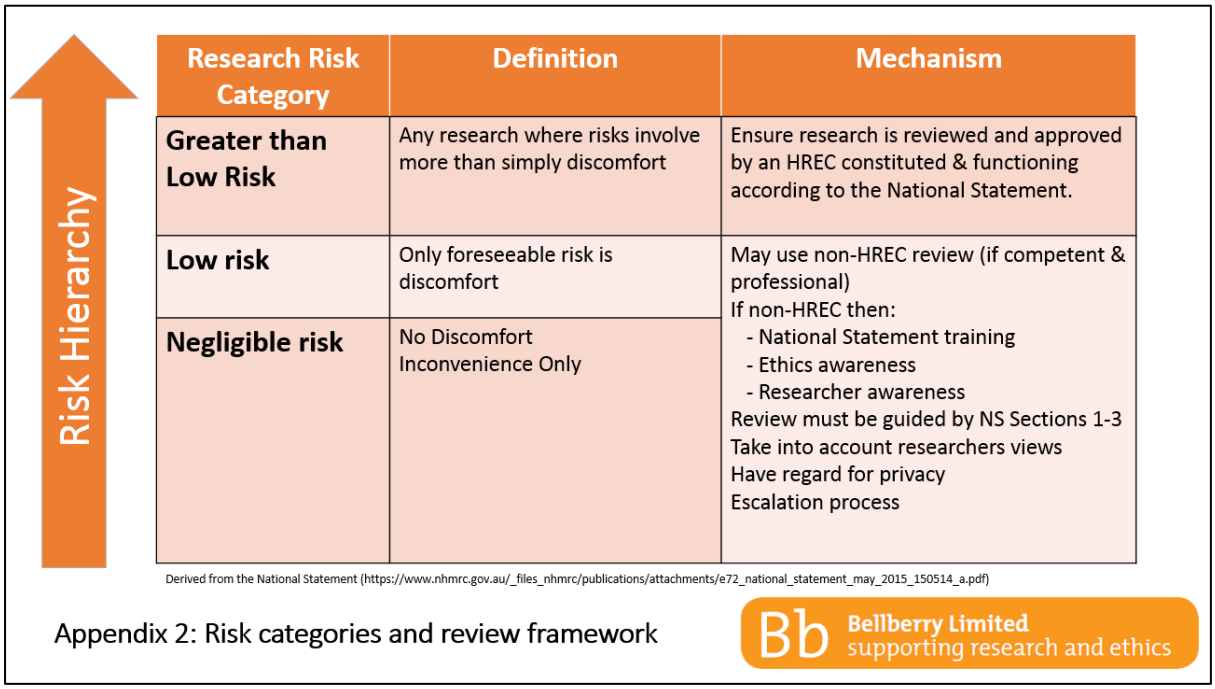
ID	Timeframe	Action	Review Recommendation Number	National Statement Mapping Reference (Appendix 1)
A	**Immediate**	Update Ethical Risk Assessment Form, Project Management Toolkit and associated Policies with recommendations from the review.	1-11 12	2, 5, 6, 8, 9, 10, 16, 21
B	**Short-Term**	Develop Policy Statements relating to: - Participant matters - Consent - Data Governance	13 15 23	
C	**Short-Term**	Develop additional elements of Research Administration: - Project templates - "Review of Review" process - Research monitoring processes - Complaints process - Research + Research Evaluation processes - Record of Committee of Peers decision making	16 17-20 21-22 24	7, 11, 13, 14, 15, 17, 19, 20
D	**Short-Term**	Review BETA and Partner Department training needs. Provide supervision by appropriately qualified staff if needed in the interim.		1, 3, 4, 18
E	**Short-Term**	Update draft Risk Spectrum (or similar) and add to Risk Assessment documentation.	11	
F	**Medium-Term**	Consider publication of the policy positions along with research summaries, in alignment with intent to publish research outcomes.	14	
G	**Long-Term**	Establish an annual review process for the research management processes and policies.	25	
	Not currently Necessary	HREC indemnifications are not necessary ahead of time, and can be undertaken as and when a study is submitted for review.		12

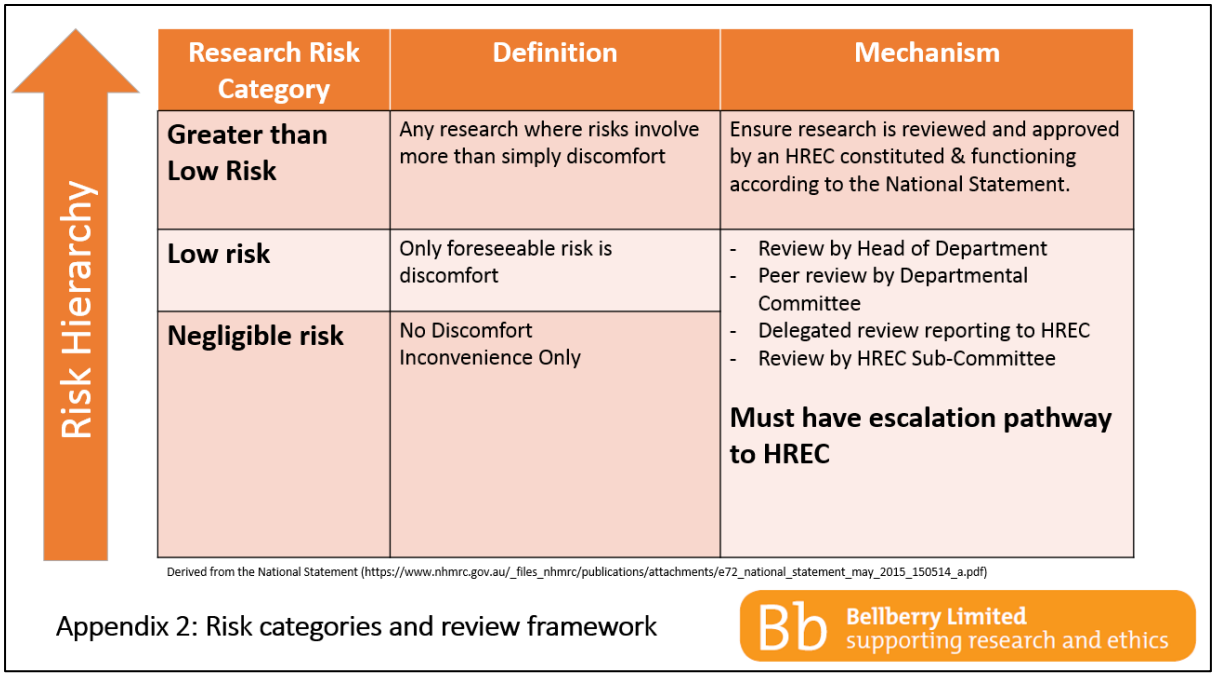
8. Appendix 1: National Statement Mapping Document – BETA Review January 2018

(Attached as Appendix 1_BETA_National Statement Mapping v1.2)

(Best viewed and printed as A3.)

9. Appendix 2: Risk Categories and Review Framework





10. Appendix 3: BETA Risk Categorisation and Review Matrix

Research Risk Category	Definition	Mechanism
Greater than Low Risk (Any research where risks involve more than simply discomfort.)	*Define what "more than simply discomfort" looks like in the context of BETA evaluation projects. For example:* - *Financial, educational, social, psychological discomfort.* - *Mental health triggers.* - *Physical interventions.* - *Targeting of sub-population level groups.* - *Differentiated interventions, or trial vs control differences.* - *Data risk/access.* *Consider any special and/or vulnerable populations who may be involved in BETA research.*	Ensure research is reviewed and approved by an HREC constituted & functioning according to the National Statement. *The National Statement is clear that research of greater than low risk to the participant must be reviewed by an HREC. BETA has committed to this in the Research Management Policy. Bellberry would recommend using an NHMRC-certified HREC, and will provide HREC services through the current service agreement.* *The inclusion of any special and/or vulnerable populations should also trigger an HREC review. Specified vulnerable populations should be read as a minimum list of examples. Other features of vulnerabilities not listed should also be considered.*
Low risk (Only foreseeable risk is discomfort)	*Define what "only discomfort" looks like in the context of BETA evaluation projects. For example:* - *Being asked to talk in front of a group of their peers.*	*BETA have nominated and described a Committee of Peers Review process. The Terms of Reference have been developed. BETA should also develop a review process (eg checklist) and recording process to document the decisions made.* *BETA must outline a review of review process, and an escalation pathway for HREC review should the risk categorisation change.*
Negligible risk (No Discomfort Inconvenience Only)	*Define what "inconvenience only" looks like in the BETA context. For example:* - *Participant entirely unaware of their involvement.* - *Acceptable and approved secondary use of data scenario.* - *Participant asked to complete minimal and non-sensitive questionnaires.* - *Participants involved anonymously.*	*BETA have developed a process and process flowchart to enable Project Manager review and assessment of this pathway. Project Managers must make reference to the National Statement in doing so.* *The Ethics Delegate will provide oversight of the risk categorisation and will have the ability to escalate in case of a difference of opinion. BETA must outline a review of review process, and an escalation pathway for HREC review should the risk categorisation change.*

Derived from the National Statement (https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf)

Appendix 3: Review framework – template built from the BETA Ethical Risk Assessment Form

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11. Appendix 4: Contents to be included in a Research Management Policy

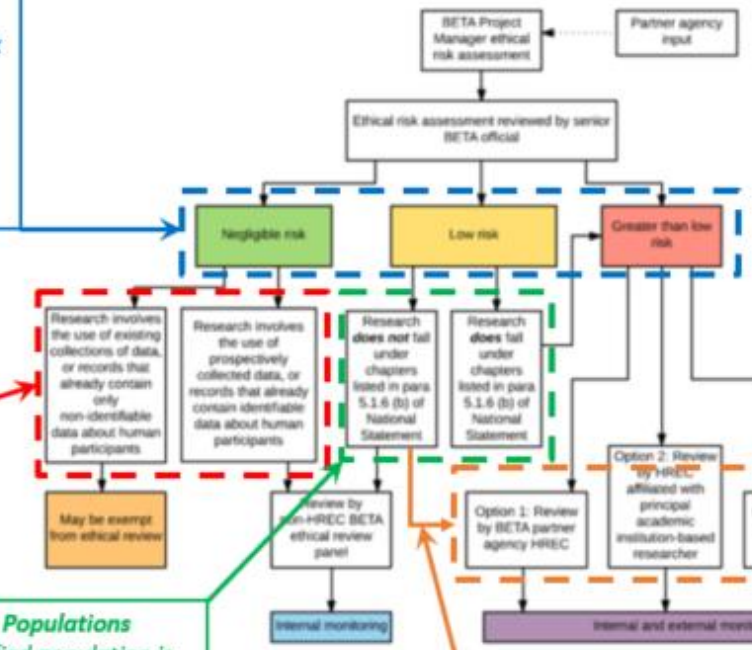
The following headings should be developed to provide standard content for a National Statement-appropriate Research Management Policy:

- Statement of corporate intent regarding ethical conduct of human research projects.
- Standards adopted (e.g. National Statement, and any others relevant to BETA and your field of research).
- Approach taken to the risk categorisation of research projects, including features of research to enable risk classification.
- Independent review and monitoring pathways to be used for each risk category.
- Escalation process to be used if risk level of a project changes.
- Consideration and treatment of special and vulnerable populations.
- Annual review process for research portfolio.
- Auditing process for research projects.
- Escalation pathway

12. Appendix 5: Suggested changes to be made to BETA Risk Assessment Flowchart

Assessment Part 1: Risk Level
- *The BETA form asks for a risk category first, before other considerations.*
- *Bellberry would suggest reviewing research features and special considerations before categorising risk level.*
- *Content and context can change the risk level.*
- *Refer to Risk Spectrum for more guidance.*

BETA Ethical Risk Identification and Management Process Flowchart



General Additions:
- *Assessment Part 3 questions and pathway is not clear on this flowchart.*
- *Risk level changes as a result of Part 3 assessments require a pathway back to the Part 1 question zone.*
- *If "yes" is answered to any question in Part 3, then greater than low risk is likely.*

Assessment Part 2:
- *Exempt from ethical review due to negligible risk level or non-identifiable use only.*
- *Be aware: content and context may change risk level.*
- *Refer to Risk Spectrum for more guidance.*

Assessment Part 2b: Vulnerable Populations
- *If a National Statement specified population is targeted, HREC review is mandated.*
- *Consider targeted population and ask whether they are a non-specified special population by looking for signs and features of "vulnerability" (e.g. domestic violence victims, historical trauma groups, power relationships etc).*
- *Refer to Risk Spectrum for more guidance.*

Additional pathway needed:
- *Risk Assessment form Part 2b notes that HREC review may still be needed – so a pathway back into HREC review should be added.*

13. Appendix 6: Draft BETA Risk Spectrum

Draft BETA Risk Spectrum.