GOVERNANCE REVIEW – New application to College Human Ethics Advisory Network

Instructions on use of this form

This form is for use by governance staff when completing governance checks of human research ethics application. Researchers can use the comments and advice provided herein to respond to the governance check.

The governance review (see main table below) consists of:

- First column: Guidance (references) to applicable policy, guidelines, regulations or legislation, to be completed by research governance staff. This includes reference to the *National Statement on Ethical Conduct in Human Research* (NS).
- Second column: Governance comments and advice, to be completed by research governance staff. All documents/items provided are reviewed, with governance comments/advice tailored accordingly.

Project title	
CHEAN reference	
Chief Investigator	

Reference	Document; item: Governance comments/advice.
Overall comment: Comment/s on the overall quality, clarity and completeness of the application (i.e. spelling/grammar, completion of all items, provision of supporting documentation etc.) and indication of degree of revision required (i.e. substantial, minor etc.). Does the application involve multiple phases? If so applicant should attach a table of explanation. Please provide the phase name/number, participants and recruitment method for each activity in a simple table.	
RMIT Human Research Ethics Application, PART A: RISK ASSESSMENT	
NS Chapter 2.1 (intro) NS 5.2.21	All items: Complete and consistent with information provided elsewhere in application? Yes/No (if no, provide details) Section 5. Outcome: Meets negligible or low risk criteria? Yes/No (if no, refer to HREC) Does checklist at 1.1.3 match risk assessment at 5?
RMIT Human Research Ethics Application, PART B: APPLICATION	
RMIT Human research ethics process NS. 1.1 (e)	Principal Investigator is an RMIT staff member? Section 1. Q1.2 – 1.4; • All investigators listed? • Contact details provided? • Adequate description of qualifications and experience? • Completed online training modules? • Are all staff and student numbers provided?

Reference	Document; item: Governance comments/advice.
NS 1.2	Section 1. Q1.5: Commencement and conclusion dates correct and consistent with information provided elsewhere?
NS 1.1 (a) - (d), 1.3, 1.4 (a)	Section 2; Q1.2: • Lay summary provided? • Aims stated along with justification? • Current literature search evident? • Clear and complete description of methodology? • Meets National Statement definition of 'human research'?
NS. Chapters 4.1 – 4.8	Section 3; Participant details: Does research involve: • Children / young people • People in dependent or unequal relationships • Peoples in other countries
NS. 1.4 (b), Chapter 2.2	If yes, have they completed additional items in Application Form and addressed relevant National Statement and other requirements? NB. The involvement of certain participant groups may also necessitate ethics review by another HREC and/or review and comment from other groups or individuals (see also Section 7).
NS. Chapter 5.1	Section 3; Q3.1: Are participant numbers correct and consistent with information provided elsewhere? Section 3, Q3.2: Is age range consistent with information provided elsewhere? (in particular, any inclusion/exclusion criteria)
NS. 5.2.23	Section 3; Q3.5: Detailed recruitment protocol provided with sufficient information to enable ethics review and consistent with information provided elsewhere in application? NB. Copies of any recruitment materials (letters of invitation, advertisements, flyers, posters etc.) provided.
NS. Chapter 3.2 and Privacy Principles	Section 4; Q4.1: If using banked data • Format in which data will be supplied, used and stored clear? • Clarification of whether persons to whom information belongs have consented to this use, provided to this banking and use? • Appropriate approval obtained from data custodian? •
NS. 2.2.1 – 2.2.3	Section 5: Q5.1: Clear and complete lay summary of research procedures provided? Lay summary consistent with information provided in the PISCF and elsewhere?
NS. 1.1 (b)	Section 5; Q5.2: If yes, copies of all research instruments provided as attachments?
NS. 1.1 (b)	Section 5; Q5.3: If yes, copies of all schedules and guides provided as attachments? Are proposed questions Negligible/ Low Risk?

Reference	Document; item: Governance comments/advice.
NS. 1.1 (f), 1.4 (c), 3.1	Section 6; Q6.1: Answered adequately? Is the use of location justified in research design? Section 6; Q6.1: If external sites are involved and permission is required, has a copy of all approvals (i.e. letter of support) been provided?
NS. Chapters 5.1 and 5.3	Section 7: Answered adequately? Section 7: If external approvals are required, has a copy of all approvals been provided? NB. Where an external Australian HREC provides ethics review and approval this will generally be recognised by RMIT University. Reviews by overseas ethics review bodies should be evaluated on a case-by-case basis.
RMIT Human research ethics process NS. 2.2.3 and 5.2.16	Section 8: Q8.1: Complete and consistent with information provided elsewhere. Section 8: Q8.3: Where information sheets and/or consent forms will be used copies provided? Section 8; Q8.4: Where information sheets and/or consent forms will be used translated copies provided, along with assurance that the translation is accurate and reliable?
NS 1.1, Privacy Principles and Health Records Act (Vic) RMIT Research data management process	Section 9: all; Is protocol for collection, use and storage of information/data for the project clear and complete? Section 9: all; Is protocol for collection, use and storage of information/data compliant with confidentiality and privacy requirements? Section 9; Q9.3.2: Is retention period specified and appropriate? Section 9.4 Is adequate information provided in the Participant Information Sheet/Consent Form?
NS. 1.5	Section 10; Q10.1: Will research outcomes be made available to participants? Is sufficient information provided in the application and PISCF including the timeliness and format? Section 10.2 & 10.3 Is this information provided in the Participant Information Statement? (If non-identifiable, 10.3 is generally not possible.)
NS. 1.6, 1.7 – 1.9, Chapter 2.1	Section 11: Are risks sufficiently described to enable ethics review? Including identification, gauging probability and severity. Section 11: Where risks are identified has researcher provided details of how these risks will be minimised and managed.
Attachments and Declaration	
	Attachments consistent with provided research instruments? Has Head of School endorsement been sought?

Reference	Document; item: Governance comments/advice.
Research Instruments	
	Copies of all research instruments provided? Ensure information is provided in application as to whether, or not, these instruments are validated.
Participant Information and/or Consent Forms	
	PICFs: Using RMIT template? If no, will need to check below and in addition contacts and complaints information. PICFs: If there is more than one participant group and/or research design will require someone to consent on behalf of participant (i.e. children, persons lacking capacity etc.), are there appropriate PICFs with content tailored to the target audience? Are translated versions required, and provided?
NS. 2.2.2	Information: Includes sufficient information on the purpose, methods, demands, risks and potential benefits of the research? Information provided is consistent with information provided elsewhere in application.
NS. 2.2.6 (a) – (m)	Information: Includes additional information as required by the National Statement (Guidelines 2.2.6 (a) – (m))? Information provided is consistent with information provided elsewhere in application.
NS. 2.2.3 and 5.2.16.	Information: Provided in lay language (approx. Year 8 – 14 year old reading level, with any technical terms/jargon explained in lay language) and in a way that is appropriate to the particular participant group.
NS. 2.2.20	Makes clear that participants are entitled to withdraw and any related consequences.
NS 2.2.16	If extended or unspecified consent is being sought, its terms and the implications are clearly stated and the PICF allows for the terms to be clearly recorded.