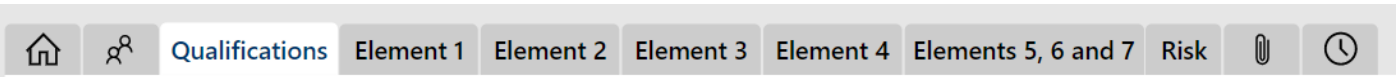
Guidelines For Researchers

What reviewers are looking for in each element of your REMS application.

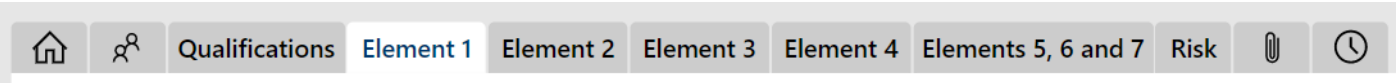
CONTACTS

- Have all members of the research team been added? If this is a student project, is a supervisor indicated?



QUALIFICATIONS

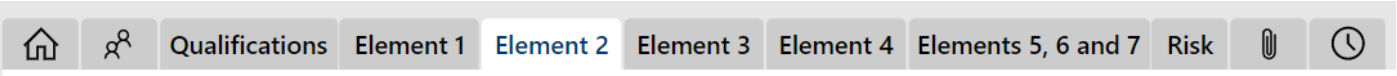
- Do the members of the research team have the qualifications to conduct the research? If not, is any training being undertaken?
- If specialist procedures are being conducted e.g. phlebotomy, do the team have the skills and are the skills and training current?
- Is anybody being supervised or trained in specialist procedures, and if so, does the trainer/supervisor have current qualifications to do so?



ELEMENT 1 - Research Scope, Aims, Themes, Questions and Methods

This element focuses on merit and integrity and how that obligation might be met. This includes scientific rigour! Merit and integrity should be assessed by standards relevant to the research field.

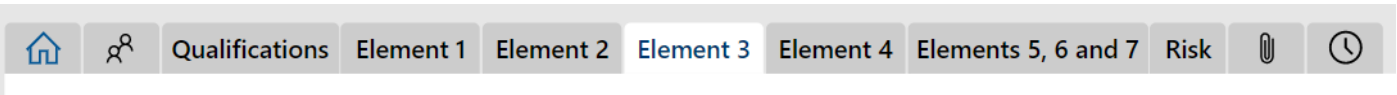
- Is the summary written in plain English, free of jargon and acronyms? If acronyms are used, are they explained on the first use?
- Are the research questions clear and unambiguous?
- Would somebody without specialist knowledge of the subject understand the scope and aims?
- For the research methods mentioned, have all appropriate attachments been included e.g. if a survey is mentioned, is a survey attached? Are the consent methods appropriate for all of the research procedures (bearing in mind that there might be several types of research procedure e.g. a survey and interview).



ELEMENT 2 - Recruitment

- Are the groups of participants clearly identified e.g. age ranges, gender, any special criteria, number of participants?
- Is recruitment clearly explained (there may be different recruitment methods for different groups)?
- Are all appropriate documents attached to the application e.g. flyer, invitation email, telephone script, verbal script?
- Have any unequal relationships been addressed e.g. tutor/student relationships, manager/employee relationships, personal contacts who may feel obliged to participate? Are management strategies for this included?
- Have any specific inclusion/exclusion criteria been included and explained? Has a justification been provided?
- Are any incentives or reimbursements being offered? Are they appropriate for the effort that the participant needs to make? Are they explained to the participant without sounding like an inducement? E.g. If offering somebody on low income $100 to complete a 5 minute survey, this would be considered an inducement.
- Do flyers/ads/invitations explain the inclusion criteria so as not to waste the time of those who are interested but ineligible?
- If email contact lists are being used, do you have permission to do this? Just because you work at a location where you may have access to this information does not mean that you have permission to use the information for a research study.

Note: Contained with the 'resources' page of the ethics website are standardised templates for Participant Information Letters and Consent Forms that researchers should use in the development of a research ethics application.



ELEMENT 3 - Consent

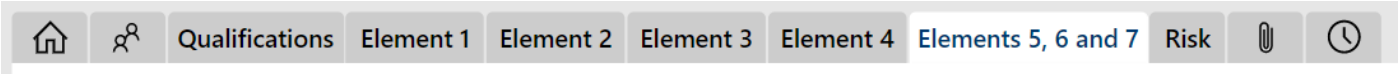
- Are all participants given the opportunity to consent in a manner that is appropriate for them e.g. child, adult, participants who may speak a language other than English?
- If children are included, has consideration been given to obtaining consent from both parent and child?
- If the project involves several stages or is longitudinal, is there provision for the researcher to reconfirm consent several times throughout the lifecycle of the project?
- If significant health findings may occur, have the participants consented to a) receiving the results b) the method that the results are conveyed to them? Note: projects which require an ethically defensive plan will require review by full HREC.
- If it is an online survey, is there a consent question at the start of the survey or a statement to indicate that completion of the survey implies consent?

- Is there provision for them to withdraw? If they withdraw what will happen to data that has already been contributed?
- Have permissions been obtained from locations, institutions, companies etc. where research is taking place (this includes if their staff are being included as participants)? If the location has a HREC and/or Governance team, they will need to be informed.
- Consent is required for the use of all social media data, even if it is publicly available (online). Where consent cannot be obtained by individuals, a researcher must seek a waiver of consent (review by full HREC).
- If government schools are being approached is Department of Education approval being sought?
- If research involves Catholic Education, then CathEd Office approval is required.
- If independent schools are included, then school principal approval is required.
- If research involves police, have WAPOL been approached?
- If research involves hospitals, has the appropriate hospital ethics committee been approached?

ELEMENT 4 - Collection, Use and Management of Data and Information

- Have all data collection methods been fully explained along with who is collecting data, where and how?
- Is there provision for group situations where some of the group are participating and some are not? E.g. a classroom situation where non-participants may need to sit in a separate area.
- Are data being collected in a way that protects anonymity where possible? If not, is this explained to the participant?
- Are participants being informed about future use of data?
- Have they been informed of all safety considerations?
- Are transcribers being used, and are they a member of the team? If not they will need to sign a confidentiality agreement.
- Is the information here consistent with the information letter/consent form?
- Is the project using publicly available data? Note: all data which are generated by humans in any way, including digital information generated by the public through their use of mobile devices and the internet, are subject to the basic principles of the National Statement which require a person's consent to use that information.
- ECU provisioned SharePoint should be used for all digital data storage. Any alternative data storage methods should be explained and justified. Digital data should not be stored on a laptop or portable device.
- Non-digital data should be protected and kept as safe and secure as is practicable during the project ie: locked in a secure location on ECU premises.

NOTE: further information regarding Data Management, Storage and Retention can be found on the Data Management Webpage



ELEMENTS 5, 6 AND 7 - Communication of Research Findings or Results to Participants; Dissemination of Project Outputs and Outcomes; After the Project

Communication

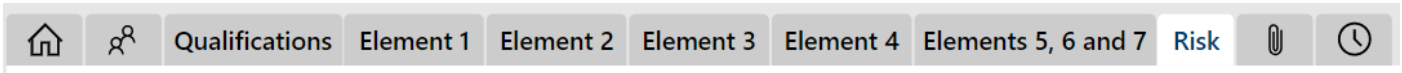
- Is there provision for participants to find out the results of the study?
- If an intervention is included, will participants (and the control group) have ongoing access if the intervention is successful?
- Does the information letter explain to participants how to obtain the results of the study?
- Could the research generate findings of interest to participants?
- Could the findings be of significance to the current or future welfare or wellbeing of participants or others? If so:
  - Are participants being forewarned of this possibility?
  - Who will communicate the findings and how?
  - Will the findings be given to third parties or the public?

Dissemination of project plan and outcomes

- What is the plan for reporting, publishing or otherwise disseminating the outputs/outcomes of the research?
- Will participants in the research be offered a timely and appropriate summary of the outputs/outcomes of the research?
- How will the planned dissemination of the outputs/outcomes of the research contribute to knowledge or practice or serve the public?

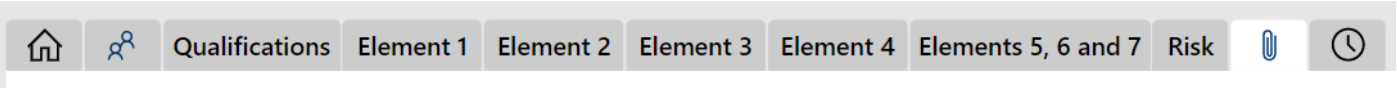
After the Project

- Responsibilities here relate to disposal or retention of data, future use of data, and any follow up or long term monitoring of participants.
- If an intervention is included, will participants (and the control group) have ongoing access if the intervention is successful?



RISK

- Are all risks adequately acknowledged and addressed with appropriate management strategies?
- Are the risk levels accurate? e.g. if emotional discomfort is mentioned and participants are provided with details of support services, this does not equate to negligible risk and will be escalated to low risk.
- Has the word ‘distress’ been used. If so, the NS equates distress to harm, and unless justified, the researcher should use alternative terminology.
- If hazardous procedures are being used, has RBHSC approval been obtained?
- Any projects with higher than low risk, vulnerable groups, ATSI participants, illegal activities, deception, waivers, opt-outs, ethically defensible plans etc. will be escalated to the HREC.



ATTACHMENTS

Have all attachments been included e.g.:

- Information letters
- Consent Forms
- Surveys and questionnaires, screening questions, medical questionnaires
- Flyers and advertisements
- Social media posts
- Invitation emails and letters
- Verbal scripts e.g. face to face, telephone
- Proposal/ concept brief (which should be consistent with the application)
- Approval/permissions from locations, institutions, companies etc
- Confirmation from supervisor that proposal has been reviewed and approved, and they are happy for ethics application to proceed.

Also refer to information letter/consent form templates on the ethics website.

Please contact the Research Ethics Team if you have any queries on 6304 2170 or email research.ethics@ecu.edu.au