

Research Integrity Unit RSC 2.1.2.1 **D23/40575** Ver 2 - 4 May 2023

Human participants checklist

About this form

- ✓ Complete this checklist if the research project involves the exposure of human participants to ionising radiation. You will need to refer to specific requirements in the <u>Radiation Protection Series (RPS) No. 8 Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes, published by ARPANSA.</u>
- Student researchers must consult with their supervisor when completing this checklist and preparing their application.

Completing the form

DO NOT COMPLETE THIS FORM IN A WEB BROWSER. You will not be able to save your data or sign the form in a browser. First SAVE this form, then OPEN the file in Adobe Acrobat Reader or Adobe Acrobat Pro.

- This checklist can be completed electronically.
- Digital forms and electronic signatures are preferred.
- If you have any questions, please contact <u>radiationsafety@csu.edu.au</u>

Submitting the application

- 1. Before submitting your application, please check that you have attached copies of all required supplementary documentation, including the **participant information sheet** prepared as part of the application to the Human Research Ethics Committee (HREC).
- 2. Ensure that <u>all</u> research team members have signed this form before submitting the application.
- 3. Submit the complete application to radiationsafety@csu.edu.au

Notification of outcome

The nominated Primary Contact will receive notification of outcome by email once the request has been considered.

Do not commence research until written approval has been received from the Radiation Safety Committee

Please note that this application only relates to the proposed use of <u>radiation</u>. If your research involves the use of animals, human subjects or restricted biological materials, separate approval may be required by the appropriate University committee. Please refer to the Research Integrity, Ethics and Compliance website

1. Research project

Project title	
Primary Contact full name (usually the Chief Investigator)	

2. Compliance

Question	Yes	Provide details			
Have you read Radiation Protection Series (RPS) No. 8 - Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes?					
Has the project been designed to consider the age, gender, pregnancy and breastfeeding status of participants, as per RPS No. 8?					
Have you applied to (or will you be applying to) the Human Research Ethics Committee (HREC)?					
Does the Participant Information Sheet include all information required by RPS No. 8?					
(ie information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure)					
Attach the Participant Information Sheet to this application.					
Explain the reasons why it is necessary to expose research participants to ionising radiation for the purpose of the research. What precautions will be taken to keep radiation exposure to a minimum?					
What is the total effective dose and relevant organ doses for the radiological procedures that will be performed as part of the research project, which are additional to those received as a part of the research participant's normal clinical management?					



Will the above dose/s exceed the dose constraints in Table 1, RPS No. 8? Provide details:	☐ Yes ☐ No
What are the risks associated with the radiation exposure in	accordance with Annex 1, RPS No. 8?
Is the site where the procedure/s are to be performed actively involved in a relevant quality assurance program, such as the programs of the Royal Australian and New Zealand College of Radiologists or of the Australian and New Zealand Association of Physicians in Nuclear Medicine?	☐ Yes ☐ No ☐ Not applicable

Remember to attach a copy of the Participant Information Sheet for the project.

3. Signature

Primary Contact

Declaration

By signing below:

- a. I certify that all details given in this proposal are correct.
- b. I have read:
 - i. the University's current radiation safety guidelines and human ethics guidelines;
 - ii. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Radiation Protection Series (RPS)
 No. 8 Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes;
 - iii. the National Health & Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research.
- c. I accept responsibility for the conduct of the research detailed in this application in accordance with the principles contained in the Statement, Code of Practice and University guidelines.
- d. I give permission for this checklist and the full application to be shared with a medical physicist selected by the RSC for the purposes of assessing or verifying doses for the radiological procedures that would be performed as part of the proposed research project.



Primary Contact Full Name	
Date	
Signature	

Instructions for submission

Once this form has been signed digitally, save and email a copy with the whole application to radiationsafety@csu.edu.au. Ensure all relevant supporting documents are attached.

For RSC meeting dates and agenda closing dates, please see the RSC meeting dates.

For HREC meeting dates and agenda closing dates, please see the <u>HREC meeting dates</u>.

To check on the status of your application, please email radiationsafety@csu.edu.au during business hours.

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Submit form and attachments to radiationsafety@csu.edu.au

Approval - RSC Use Only		
Protocol Number	Signature	Date
	RSC Presiding Officer	

