

# Ionising Radiation in Clinical Research Guidelines

These guidelines are designed to give applicants the current documents, templates and information to complete the ionising radiation component of applications being submitted to the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)

## How to use this document:

In certain circumstances general research, clinical drug and medical device trials can require ionising radiation methods. If the proposed research involves exposing participants to ionising radiation above the current standard of care the Radiation Control Branch of the Environment Protection Authority (EPA) will need to be notified and a Radiation Dose Report submitted as part of the SAC HREC application.

## Background:

*Regulation 43 of the Radiation Protection and Control Regulations 2015* requires the principal researcher to notify the Radiation Protection Branch of their intention to undertake research involving exposure of research participants to ionising radiation above that required as part of normal clinical management prior to the research commencing.

- > Research proposals using ionising radiation methods are required to document: procedures to be used; the apparatus; radioactive sources; the number and frequency of procedures per participant per year; the number and frequency of procedures per participant over the course of the project; where the procedures will be carried out.
- > To notify the EPA download the [Research Study Involving Exposure of Humans to Ionising Radiation form](#)  
Complete all parts and return by email to [radiationprotection@epa.sa.gov.au](mailto:radiationprotection@epa.sa.gov.au) or post to:  
Radiation Protection  
Environment Protection Authority  
GPO Box 2607  
Adelaide SA 5001
- > The Radiation Dose Report (required by the SAC HREC) will document the dose estimates and associated risks within the research project. The researcher is required to engage the services of a Radiation Safety Adviser, who will author the Radiation Dose Report. The PICF must reflect the outcomes of this report.
- > [EPA - radiation research involving humans](#)
- > [Full list of Radiation legislation administered by the EPA](#)

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For more information

**Office for Research  
SAHLN**  
Telephone: (08) 8204 6453  
[www.sahealth.sa.gov.au/SALHNresearch](http://www.sahealth.sa.gov.au/SALHNresearch)

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