Radiation Assurance Consistency Review Criteria

Initial checks

On receipt of a submission for Radiation Assurance, but prior to the Radiation Assurance consistency review occurring, the HRA will ensure that the following criteria are met:

a. The study involves research exposures to ionising radiation.
b. The study type is within the current phase of roll-out.

Studies which do not meet the above criteria will not be accepted through Radiation Assurance.

The HRA will then ensure that the minimum document set has been submitted before proceeding any further:

a. Protocol
b. IRAS form
c. Research exposure form
d. Any participant information sheets and consent/assent forms

Applicants should note that other documents may be required to be submitted depending on the submission route (self-managed or HRA-managed) and the requirements of the study e.g. imaging manual. Further details are provided in the below section.

Radiation Assurance consistency review criteria

An application will be accepted for expert review if it meets the criteria in the following items. In order to conduct the consistency review, the HRA will review all the submitted documents, ensuring the following:

a. Details of any radiation exposures (both ionising and non-ionising) are consistent throughout the application with no discrepancies or contradictions between documents.

b. The following sections of the IRAS form are completed: project filter page; A13; A19; and A22. The maximum number of exposures for each procedure should be included in the IRAS form.

c. The applicant has completed section F1 of the research exposure form. The form must be the version in use at the time of the initial submission, which is available on the IRAS website.

d. As a minimum, a section is available to provide information about risk of exposure to ionising radiation in all participant information sheet(s) and consent/assent form(s) and any other relevant participant facing documents.

e. That, if appropriate for the study, an imaging manual or equivalent has been submitted. The HRA will request this document if not previously provided.

f. That, if appropriate for the study, a radiotherapy protocol has been submitted; or sufficient information on any radiotherapy is provided in the main protocol. The HRA will request this document if not previously provided

g. That all sponsor submitted documents are marked with version numbers and dates.

Additional Radiation Assurance consistency review requirements for HRA-managed studies

Applicants should note that this section only applies where specific trusts/health boards and/or reviewers are requested. Where this is the case the HRA will ensure that:

a. The Radiation Assurance registered reviewer request form has been submitted and completed with all the requested information present.

b. The trusts/health boards listed are included on the HRA-registered reviewer list and that they can provide reviewers to conduct the HRA-managed review with the required modalities and specialisms for the study.

c. Where reviewers are specified, that they are on the HRA-registered reviewer list to conduct HRA-managed reviews and that they have modalities and specialisms as required for the review to be conducted

Additional Radiation Assurance consistency review requirements for self-managed studies

The HRA will ensure that:

a. The Radiation Assurance self-managed study registration form has been submitted and completed with all the required information.

b. All reviewers listed are on the HRA-registered reviewers list as self-managed reviewers and have the required modalities and specialisms for the review to be completed.