Radiation Assurance Consistency Review Guidance

When you submit an application for Radiation Assurance it will undergo a consistency review by HRA staff. This ensures the Medical Physics Expert (MPE) and/or Clinical Radiation Expert (CRE) have all the information they need for their assessments.

In this document you can find the criteria that HRA staff check applications against when carrying out the consistency review. You'll also find guidance on what we recommend you check when you begin preparing an application for Radiation Assurance to help ensure it passes the consistency review.

Radiation Assurance Consistency review criteria

HRA staff will review your application against the following criteria to ensure all necessary information has been provided and is consistent before they forward it to the MPE/CRE.

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

b) The necessary sections of the relevant IRAS form must be completed - for information on what sections of IRAS need to be completed and submitted you should view the "Confirm what documents you should submit" section of this guidance.

c) Section F1 of the research exposure form has been completed. 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 sheets and consent/assent forms and any other relevant participant facing documents

e) If appropriate for the study, an imaging manual or equivalent has been submitted. The HRA will request this document if not previously provided, or if there is an indication that one is available within study documentation, (meaning the study protocol).

f) 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, or if there is an indication that one is available within study documentation (meaning the study protocol).

g) All sponsor submitted documents are marked with version numbers and dates.

Additional Radiation Assurance consistency review requirements for HRA-managed studies

You 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.

c. No reviews have been conducted by an MPE/CRE prior to submission to Radiation Assurance. Reviews should not be completed before submission as the content of what you submitted for these reviews may need to change following completion of the consistency review.

Tips to help your application to pass the consistency review

When applications do not pass the consistency review this is typically due to:

- the research not being eligible for Radiation Assurance
- the submission not including the required documents
- inconsistencies between the documents in how they describe ionising radiation exposure

In this section you'll find guidance on what you should check before you begin or submit an application to Radiation Assurance so it will pass the consistency review as quickly as possible.

Confirm your study is eligible

HRA staff conducting a consistency review will initially check to ensure your study is eligible for Radiation Assurance. Before you begin preparing an application for Radiation Assurance you should confirm your study is eligible. Your study is eligible if it:

- involves research exposures to ionising radiation
- is taking place in secondary care within the NHS/HSC

If your study meets both of the above criteria you should proceed with preparing an application for Radiation Assurance.

Confirm what documents you should submit

For your application to pass the consistency review you need to ensure all documents the HRA staff expect have been submitted.

The documents you'll need to submit depends on whether your application:

- Is being submitted by combined review
- will involve nuclear medicine and will therefore need to be assessed by the Administration of Radioactive Substances Advisory Committee (by ARSAC)
- is being submitted by the HRA or self-managed route for Radiation Assurance.

The below table describes what documents you should submit depending on your study design.

Documents	Combined review application (without nuclear medicine)	Combined review application (including nuclear medicine)	Non-Combined review application (without nuclear medicine)	Non-Combined review application (including nuclear medicine)
Protocol	YES	YES	YES	YES
Any participant information sheets and consent/assent forms (with a section of text relating to ionising radiation risk)	YES	YES	YES	YES
Standard IRAS Form with the filter page, A13 and A19 completed	NO	YES	YES	YES
Standard IRAS Form with A22 completed	NO	NO	YES	YES
New IRAS Form with B2, B4, F1 and F2 completed	YES	YES	NO	NO
Research Exposure Form (with section F1 completed)	YES	YES	YES	YES
Imaging Manual (if available)	YES	YES	YES	YES
Radiotherapy Manual (if applicable to modalities included)	YES	YES	YES	YES
'Self-managed Study Registration Form' or the 'HRA-	YES	YES	YES	YES

Documents	Combined review application (without nuclear medicine)	Combined review application (including nuclear medicine)	Non-Combined review application (without nuclear medicine)	Non-Combined review application (including nuclear medicine)
Managed Study - Reviewing Trust/Health Board Request Form' *(depending on which route you submit your application by)*				

The templates for some of these documents (for example the Research Exposure Form, the Self-Managed Study Registration Form and the HRA-Managed Study Reviewing Trust/Health Board Request Form) are available in our 'Radiation Assurance' page on the IRAS website.

Confirm your documents are consistent

If your documents have inconsistencies in how they describe radiation exposures this will be queried during the consistency review, causing unnecessary delays. Before you submit you should ensure the research exposure form (REF) is consistent with your other study documents, particularly your IRAS form.

The documents you'll need to submit depends on your study type. In particular whether your study is a combined review application and if it involves nuclear medicine that would require assessment by the Administration of Radioactive Substances Advisory Committee (ARSAC).

You should review the guidance relevant to your study type for information on what you need to check is consistent

- Non-combined review application involving nuclear medicine (ARSAC Application needed)
- Non-combined review application not involving nuclear medicine
- Combined review applications involving nuclear medicine (ARSAC Application needed)
- Combined review applications not involving nuclear medicine

Non-combined review application involving nuclear medicine (ARSAC Application needed)

If your application is not a combined review application (meaning it is not a CTIMP or a combination trial of an investigational medicinal produce and device) you should ensure the following sections of the standard IRAS form are completed.

i. The project filter page
ii. A13 (detailing the maximum number of research exposures for each procedure)
iii. A19 (detailing the maximum number of research exposures for each procedure)
iv. A22 (detailing the maximum number of research exposures for each procedure)

If you're submitting a study involving the use of nuclear medicine you should ensure the full details of the radionuclides to be used in any nuclear medicine procedures are detailed in the Research Exposure Form (REF) in Part 2, column 3. In the event of any uncertainty, or where there are site variations, you should discuss this with sites as required. You should also review the ARSAC notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources.

You should ensure the following information is consistent across the documentation:

Research Exposure Form (Section F1)	**A19 of the standard IRAS form**
'Procedure' column	Intervention or procedure column
'Maximum possible examinations for maximum possible time in study' column	Column 1 – total number of interventions/procedures to be received by each participant as part of the research protocol
'Approximate number routine care – including frequency/timepoints' column	Column 2 – If this intervention/procedures would be routinely given to participants as part of their care outside the research, how many of the total would be routine?

Non-combined review applications not involving nuclear medicine (no ARSAC Application needed)

If your application is not a combined review application (meaning it is not a CTIMP or a combination trial of an investigational medicinal produce and device) you should ensure the following sections of the standard IRAS form are completed.

i. The project filter page
ii. A13 (detailing the maximum number of research exposures for each procedure)
iii. A19 (detailing the maximum number of research exposures for each procedure)
iv. A22 (detailing the maximum number of research exposures for each procedure)

You should ensure the following information is consistent across the documentation:

Research Exposure Form (Section F1)	**A19 of the standard IRAS form**
'Procedure' column	Intervention or procedure column
'Maximum possible examinations for maximum possible time in study' column	Column 1 - total number of interventions/procedures to be received by each participant as part of the research protocol
'Approximate number routine care - including frequency/timepoints' column	Column 2 - If this intervention/procedures would be routinely given to participants as part of their care outside the research, how many of the total would be routine?

Combined review applications involving nuclear medicine (ARSAC Application needed)

If your study will be a combined review application involving nuclear medicine (meaning an ARSAC application is needed) then you'll need to complete the following sections in the standard part of IRAS.

i. The project filter page
ii. A13 (detailing the maximum number of research exposures for each procedure)
iii. A19 (detailing the maximum number of research exposures for each procedure)

You'll also need to complete these sections in the new part of IRAS.

I. "Study information B2 Clinical interventions" – When completing columns two, three and four please specify the maximum possible number of procedures
I. "Study information B4 What are the potential risks and burdens for research projects and how will you minimise them?"
II. "Study information F1 Does the study involve exposure to radioactive materials?"
III. "Study information F2 Does the study involve other diagnostic or therapeutic ionising radiation?"

If you're submitting a study involving the use of nuclear medicine you should ensure the full details of the radionuclides to be used in any nuclear medicine procedures are detailed in the Research Exposure Form (REF) in Part 2, column 3. In the event of any uncertainty, or where there are site variations, you should discuss this with sites as required. You should also review the ARSAC notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources.

You should ensure the following information is consistent across the documentation:

B2 of the combined review IRAS form	**Research Exposure Form (section F1)**	**A19 of the standard IRAS form**
Column 1 – 'Interventions/procedures to be received by each participant as part of the research protocol'	"Procedure" column	"Intervention or procedure" column
Column 4 – 'Total number of interventions/procedures'	"Maximum possible examinations for maximum possible time in study" column	Column 1 – "Total number of interventions/procedures to be received by each participant as part of the research protocol"
Column 2 – 'Number of interventions/procedures which are part of standard care'	"Approximate number routine care – including frequency/timepoints" column	Column 2 – "If this intervention/procedures would be routinely given to participants as part of their care outside the research, how many of the total would be routine?"

Additionally, in column 3 of part B2 of the combined review IRAS form you'll be asked to enter the number of interventions/procedures that are additional to standard care. Whilst there's no section specifically asking about this in the REF or A19 of the standard IRAS form, you should ensure the details you enter into these documents (meaning the difference between what value you enter as the maximum/total number of exposures and what you enter as being the number that are standard of care) is consistent your response to column 3 of the combined review IRAS form

Combined review applications not involving nuclear medicine (no ARSAC Application needed)

If your application is a combined review application not involving nuclear medicine then in the new part of IRAS you should complete:

I. "Study information B2 Clinical interventions" - When completing columns two, three and four please specify the maximum possible number of procedures
II. "Study information B4 What are the potential risks and burdens for research projects and how will you minimise them?"
III. "Study information F1 Does the study involve exposure to radioactive materials?"
IV. "Study information F2 Does the study involve other diagnostic or therapeutic ionising radiation?"

You should ensure the following information is consistent across the documentation:

B2 of the combined review IRAS form	**Research Exposure Form (section F1)**
Column 1 – 'Interventions/procedures to be received by each participant as part of the research protocol	"Procedure" column
Column 4 – 'Total number of interventions/procedures'	"Maximum possible examinations for maximum possible time in study" column
Column 2 – 'Number of interventions/procedures which are part of standard care'	"Approximate number routine care - including frequency/timepoints" column

Additionally, in column 3 of part B2 of the combined review IRAS form you'll be asked to enter the number of interventions/procedures that are additional to standard care. Whilst there's no section specifically asking about this in the REF, you should ensure the details you enter into the REF (meaning the difference between what value you enter as the maximum number of exposures and what you enter as being the number that are standard of care) is consistent your response to column 3 of the combined review IRAS form

Providing Feedback

We welcome all feedback on the Radiation Assurance process and the associated guidance. You can provide any feedback you have by emailing us at radiation.assurance@hra.nhs.uk