

F1: To be completed by the applicant

Radiation Assurance Research Exposure Form

F1: To be completed by the applicant

This section is to be completed by the applicant before submission of the application for Radiation Assurance. The HRA will then conduct a consistency review of the application prior to assigning the study for review by a lead CRE and MPE and any additional reviewers required.

Give as much information as possible referring to the notes at the end of each part of F1. These give guidance regarding the level of detail required within the tables.

If you require additional rows to be provided please email radiation.assurance@hra.nhs.uk, specifying which areas of the form require additional rows and how many.

Short study title	PhEAST
IRAS project ID	304658
EudraCT number (CTIMPs only)	N/A
Estimated start date	Started 27/05/2022
Estimated end date	28/02/2025
Median length of participation <i>(how long are participants in the study?)</i>	12 months
Is this submission a pre-regulatory approval submission to Radiation Assurance or an amendment? <i>If it is related to an amendment, please provide the sponsor amendment reference as listed on the notice of substantial amendment form</i>	Amendment - SA_04_22

Prognosis, median life-expectancy and median time-to-progression	
Age (specify numerically e.g. 21 – 60 years)	18-110
Sex	Male and female
Where applicable: Median time to disease progression	N/A
Median survival times (where relevant)	N/A
Maximum time in the study	12 months

Does this study involve:	Yes	No
Radiology? <i>If "Yes", complete part 1</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Radioactive substances? <i>If "Yes", complete part 2</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Radiotherapy? <i>If "Yes", complete part 3</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Non-ionising radiation? <i>If "Yes", complete part 4</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

F1: To be completed by the applicant

	Y	N
Do the participant information sheets have a radiation risk statement?*	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>If yes, please insert below:</i>		

*If no, the MPE will provide a radiation risk statement for the participant information sheet (PIS) in C1. This should be added to the PIS prior to authorisation being requested. The MPE and CRE should not authorise the IRAS form until the PIS has been updated accordingly.

F1: To be completed by the applicant

Part 1: Radiology ionising radiation imaging procedures

1	2	3	4	5	6	7	8
Participant cohort ^a	Procedure ^b	Body part / exam protocol ^c	Frequency / study point ^d	Maximum possible examinations for maximum possible time in study ^e	Maximum examinations for median time in study	Approximate number routine care – including frequency / time points ^f	Reporting & copy images required ^g
N/A	X-Ray	Chest	If needed at time of tube replacement (NG to Phagenyx catheter, Phagenyx catheter to NG)	3	3	1 may be needed each time an NG tube is placed.	NO

If the study has an open ended design which makes it impossible to determine the maximum examinations required by the protocol you should use a separate row for every year for which the study will be open. Where there is no year to year variation, it is acceptable to title the information 'Years 3—17', for example.

	Y	N
Is a phantom scan/study required as part of the trial? If 'yes' please give details in the table below	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Comments (to include variations between sites):
When randomised to receive PES-treatment, if a participant already has an NG tube in situ, they need this replacing with the Phagenyx catheter. We advise to follow local policies and procedures with regards to placement, which may be obtaining aspirate, and then if this is not possible, a chest x-ray. When the PES catheter is removed, if the participant still needs enteral feeding via an NG tube, they may need aspirate and/or chest x-ray again to confirm placement.

Notes

^a e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.

^b e.g. 'Triple-phase CT scan' not 'CT scan'.

^c e.g. 'Chest, abdomen and pelvis', not 'torso'. Where a whole body scan is utilised it should be clear if this is head-to-toe, head-to-pelvis, or neck-to-pelvis.

^d e.g. 'Baseline, then every 8 weeks'.

^e The entry should be the same as IRAS A19 column 1.

^f This should be the number of examinations in column 5 that could be considered routine care. The entry should be the same as IRAS A19 column 2.

F1: To be completed by the applicant

⁹ e.g. 'RECIIST'.

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Part 2: Administration of radioactive substances or brachytherapy (including non-imaging procedures such as GFR)

1	2	3	4	5	6	7	8	9
Participant cohort ^a	Procedure ^b	Radioactive substance / Radio-pharmaceutical	Body part / exam protocol ^c	Frequency / study point ^d	Maximum possible examinations for maximum possible time in study ^e	Maximum examinations for median time in study	Approximate number routine care – including frequency / time points ^f	Specify any study protocol-specific reporting and / or data processing required? ^g

If the study has an open ended design which makes it impossible to determine the maximum examinations required by the protocol you should use a separate row for every year for which the study will be open. Where there is no year to year variation, it is acceptable to title the information 'Years 3—17', for example.

Is there any requirement for pre-trial site validation? e.g. submission of phantom study and / or other QA procedure(s), camera system calibration / accreditation, data transfer testing? If 'yes' please give details in the table below	Y	N
	<input type="checkbox"/>	<input type="checkbox"/>

Comments (to include variations between sites):

Notes

^a e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.

^b e.g. MUGA study, whole body phosphonate bone scan, GFR study, dynamic renogram, total body FDG PET/CT, amyloid brain PET/CT. Not cardiac scan, bone imaging, renal function test, PET/CT, brain PET.

^c e.g. 'Chest, abdomen and pelvis', not 'torso'. Where a whole body scan is utilised it should be clear if this is head-to-toe, head-to-pelvis, or neck-to-pelvis.

^d e.g. 'Baseline, then every 8 weeks'.

^e The entry should be the same as IRAS A19 column 1.

^f This should be the number of examinations in column 6 that could be considered routine care. The entry should be the same as IRAS A19 column 2.

^g e.g. e.g. lesion scoring, SUV analysis, quantification, structured reporting

F1: To be completed by the applicant

Part 2 continued: Administration of radioactive substances

The following questions are duplicated from IRAS (Part B Section 3 - A2 and A3 and ARSAC form). These sections are expected to be completed prior to MPE/CRE review and they should be consistent with the information in IRAS.

	Y	N
Will any of the study participants be patients?	<input type="checkbox"/>	<input type="checkbox"/>

If yes, please complete the table below for the patient group involved in the study. Where multiple patient groups are involved please contact radiation.assurance@hra.nhs.uk so that additional tables can be added:

Details of patients to be studied	
Number (whole study)	
Age range (specify numerically e.g. 21 – 60 years)	
Sex	
Clinical condition	

	Y	N
Will any of the study participants be healthy volunteers?	<input type="checkbox"/>	<input type="checkbox"/>

If yes, please complete the table below for the healthy volunteer group involved in the study. Where multiple healthy volunteer groups are involved please contact radiation.assurance@hra.nhs.uk so that additional tables can be added:

Details of healthy volunteers to be studied	
Number (whole study)	
Age range (specify numerically e.g. 21 – 60 years)	
Sex	

What steps will you take to exclude individuals who are pregnant or who could become pregnant during the study? <i>Give details of screening procedures and advice to be given to women of child-bearing age (to be copied into IRAS A3)</i>

F1: To be completed by the applicant

Part 3: Radiotherapy procedures (include number of treatment fractions, all pre-treatment imaging e.g. CT, PET/CT, 4DCT and all on-treatment imaging)

Use separate rows as necessary for each treatment phase and/or treatment arm(s), and for each imaging modality whether pre-treatment or on-treatment.

1	2	3	4	5	6	7	8	9
Participant cohort ^a	Procedure ^b	Treatment site and phase	Dose prescription(s), protocol ^c	Technique, protocol ^{d or e}	Dose prescription, routine care ^c	Technique, routine care ^{d or e}	Number of exposures, protocol ^{f, g}	Number of exposures, routine care ^{f, h}
	Please Select:							
	Please Select:							
	Please Select:							
	Please Select:							
	Please Select:							
	Please Select:							

Are there any radiotherapy QA requirements for the trial? If yes, please brief details of pre-trial QA e.g. outlining, planning and / or phantom measurements plus any on-going trial QA and data transfer requirements in the comments box	Y <input type="checkbox"/>	N <input type="checkbox"/>
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Comments (to include variations between sites):

Notes

^a e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.

^b e.g. radiotherapy treatment, planning CT (include repeat CT planning scans if part of protocol e.g. for adaptive radiotherapy), treatment verification.

^c Completion of this field is required for treatment procedures only. E.g. 50 Gy in 25 fractions over 5 weeks, include for each phase of treatment or trial arm.

^d e.g. single applied field, electron, 3D conformal, IMRT, volumetric/arc therapy.

^e e.g. 3D or 4D for planning CT; kV, MV or CBCT for verification.

^f where this relates to the radiotherapy treatment you should specify the maximum number of fractions, not number of treatments. Where this relates to pre or on-treatment imaging you should specify the maximum number of exposures.

^g The entry should be the same as IRAS A19 column 1.

^h This should be the number of examinations in column 8 that could be considered routine care. The entry should be the same as IRAS A19 column 2.

F1: To be completed by the applicant

Part 4: Non-ionising radiation imaging procedures (to aid feasibility at sites)

Give as much information as possible. Refer to the notes at the end of section F1 which give guidance regarding the level of detail required within the table.

1	2	3	4	5	6	7	8
Participant cohort ^a	Procedure ^b	Scan extent –body part / exam protocol ^c	Frequency / study point ^d	Maximum possible examinations for maximum possible time in study ^e	Maximum examinations for median time in study	Approximate number routine care – including frequency / time points ^f	Reporting & copy images required ^g

If the study has an open ended design which makes it impossible to determine the maximum examinations required by the protocol you should use a separate row for every year for which the study will be open. Where there is no year to year variation, it is acceptable to title the information ‘Years 3—17’, for example.

Notes

^a e.g. ‘cohorts 1 - 3’ or ‘all cohorts’. Where there are no cohorts then ‘N/A’ would be acceptable.

^b e.g. ‘Triple-phase CT scan’ not ‘CT scan’.

^c e.g. ‘Chest, abdomen and pelvis’, not ‘torso’. Where a whole body scan is utilised it should be clear if this is head-to-toe, head-to-pelvis, or neck-to-pelvis.

^d e.g. ‘Baseline, then every 8 weeks’.

^e The entry should be the same as IRAS A19 column 1.

^f This should be the number of examinations in column 6 that could be considered routine care. The entry should be the same as IRAS A19 column 2.

^g e.g. ‘RECIST’.

F2: To be completed by the MPE

F2: To be completed by the MPE

This section is to be completed by the MPE after the HRA has completed their consistency review of the application. The information reflects that which is presented in IRAS and once it is completed will be transferred into IRAS by the applicant. Additional guidance for information required within the review can be found on the IRAS question-specific guidance and in the MPE review procedure guidance.

If additional tables are required within F2 please contact radiation.assurance@hra.nhs.uk.

	Y	N
1. Does the study involve exposure to radioactive materials? If "Yes", complete part A	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. Does the study involve other diagnostic or therapeutic ionising radiation? If "Yes", complete part B	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Part A: Radioactive materials (IRAS part B section 3 - A)

Complete the table below for each radioactive substance to be administered (IRAS part B section 3 A1)

Please complete the table below for each radioactive substance administered/procedure undertaken:

Type of investigation / therapy	
Radionuclide*	
Chemical form	
Proposed activity (MBq)	
Route of administration	
Maximum number of administrations per participant	
Effective dose or target-tissue dose per administration (specify units)**	

*Radioactive substance

**Please include references here

Details of study participants (IRAS part B section 3 A2)

	Y	N
Will any of the study participants be patients?	<input type="checkbox"/>	<input type="checkbox"/>

If yes, please duplicate and complete the table below for each patient group involved in the study:

Details of patients to be studied	
TOTAL dose or target tissue dose per individual (specify units)	

	Y	N
Will any of the study participants be healthy volunteers?	<input type="checkbox"/>	<input type="checkbox"/>

If yes, please duplicate and complete the table below for each healthy volunteer group involved in the study:

Details of healthy volunteers to be studied	
TOTAL dose or target tissue dose per individual (specify units)	

	Y	N
Is the statement (referenced in F1) regarding pregnancy appropriate? If no, please provide comment below.	<input type="checkbox"/>	<input type="checkbox"/>

F2: To be completed by the MPE

Part B: Other ionising radiation (IRAS part B section 3 - B)

Details of other ionising radiation (to reflect IRAS part B section 3 B1)

Information about all ionising radiation not listed above, specify the following:

Type of investigation / procedure	Number of procedures ¹	Estimated procedure dose (per investigation) in mSv ²
Chest X-ray	3	Effective dose of 0.02 mSv

¹As stated in Section F1

²Use national diagnostic reference levels, where available. Any references used to calculate estimated procedure dose should be included here and copied in IRAS part B section 3 B1.

Part C: Dose risk assessment (IRAS part B section 3 - C)

Note to applicant – Please ensure that **all** completed sections below are copied into the IRAS form in part B section 3 question C1.

<p>What is the total participant dose from all the exposures in A1 and / or B1, and what component of this is the additional dose over and above standard practice? What are the risks associated with these two doses (total and additional)? (IRAS part B section 3 – C1)</p> <p><i>This should be prepared by a Medical Physics Expert (MPE) who is a clinical scientist registered with the Health and Care Professions Council and has expertise relevant to the planned exposures. Where the study involves different types of exposure (for example, both radioactive materials and other ionising radiation, or more than one imaging method), advice may need to be sought from other MPEs with relevant expertise. The lead MPE should produce a combined assessment, giving the names of any other MPEs who have contributed to the assessment.</i></p> <p><i>Consideration should be given as to whether the exposures listed in part F1 of this form as standard of care are appropriate.</i></p> <p><i>Please list all of the reviewers who have contributed to this review.</i></p> <p><i>Please state if any of the reviewers are part of the research team or named in the protocol.</i></p>		
<p>Study participants may receive chest X-rays on a maximum of 3 occasions, some or all of these exposures being in addition to standard care.</p> <p>The total protocol dose (based on average sized patients) is estimated as 0.06 mSv.</p> <p>This dose estimate is based on national diagnostic reference levels (DRLs) and report HPA-CRCE-028 of the UK Health Security Agency, which indicates that the national DRL for a PA chest X-ray is equivalent to approximately 0.02 mSv.</p> <p>For a participant in normal health, there would be an extra risk of cancer induction due to exposure to radiation. For a 30-40 year old individual in normal health, the estimated lifetime risk of cancer associated with the total protocol dose (0.06 mSv) is 1 in 250,000 (using age-specific risk coefficients from the HPA-CRCE-028 report). The older the patient the lower the risk.</p> <p>For comparison, the natural lifetime cancer incidence in the general population is about 1 in 2.</p>		
Has a risk statement been provided by the applicant for the participant information sheet?	Y <input type="checkbox"/>	N <input checked="" type="checkbox"/>
If yes, is the risk statement provided acceptable?	Y <input type="checkbox"/>	N <input checked="" type="checkbox"/>

F2: To be completed by the MPE

If either of the above are answered no, please comment below. (IRAS part B section 3 – C1)

Any required changes to the participant information sheet(s) should be noted here and uploaded onto IRAS as part of the review so that REC & governance reviewers can satisfy themselves that the required changes (and no others) have been made post-MPE review to the sections of the participant information sheet(s) relating to research exposures.

Participant information sheet statement inserted below:

As part of the study you may receive up to 3 chest X-rays, some of which you would not have had if you did not take part.

X-rays are a form of ionising radiation and are used to create images of your body. The risk of exposure to radiation is that you may develop cancer some years in the future.

1 in 2 people in the UK will develop cancer at some point in their lifetime. Taking part in the study will increase the chance of this happening to you by only a very small amount.

Details of lead MPE (IRAS part B section 3 – C3):

Title	Ms
Forename	Catherine
Surname	Taylor
Organisation	The Christie NHS Foundation Trust
Address	Wilmslow Road, Manchester, M20 4BX
Telephone	0161 446 3537
Mobile	07947764808
E-mail	catherine.taylor210@nhs.net
Professional position	Principal Clinical Scientist
HPCP professional registration	CS18602
MPE registration number	678

For the purposes of Radiation Assurance only (not to be copied into IRAS):

Lead MPE's HRA registered reviewer number	HRA83339RA
If different to the above, e-mail used for IRAS authorisation	

F3: To be completed by the CRE

F3: To be completed by the CRE (IRAS part B section 3 - D)

This section is to be completed by the CRE after the HRA has completed their consistency review of the application. The information provided by the CRE will be transferred into IRAS by the applicant. Additional guidance for information required within the review can be found on the IRAS question-specific guidance and in the CRE review procedure guidance.

Assessment of additional exposures (IRAS part B section 3 D2)

Note to Applicant – Please ensure that **all** completed sections below are copied into the IRAS form in part B section 3 question D2.

	Y	N
(IRAS part B section 3 D1) Will the exposure to ionising radiation exceed the exposure that might be received as part of normal care at any proposed research site? If “yes”, complete question below.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
What is the total participant dose from all the exposures in A1 and / or B1, and what component of this is the additional dose over and above standard practice? What are the risks associated with these two doses (total and additional)? (IRAS part B section 3 D2)		
Explain how the planned exposure compares with normal practice and assess whether it is appropriate, using language comprehensible to a lay person. <i>Consideration should be given to the specific objectives of the exposure in relation to the study objectives, the characteristics of participants, the potential diagnostic or therapeutic benefits to the participant, the potential benefits to society, the risk to the participant and the availability of alternative techniques involving less, or no, ionising radiation.</i> <i>Consideration should also be given as to whether the exposures listed in part F1 of this form as standard of care are appropriate.</i> <i>Please list all of the reviewers who have contributed to this review.</i> <i>Please state if any of the reviewers are part of the research team or named in the protocol.</i>		
This study includes adult participants with recent ischaemic or haemorrhagic stroke with clinical dysphagia. The clinical outlook and prognosis of most of the participants in this study is moderately lowered compared to the general population. They will receive additional radiation burden, which is above that anticipated in routine clinical care. The risk of harm from the additional radiation burden is justified as it is essential to provide objective assessment during the trial.		
Participant information sheet (IRAS part B section 3 D2)		
Is the information provided in the PIS suitable for participants with this clinical condition?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If no, please comment below. <i>Any required changes to the participant information sheet(s) should be noted here and uploaded onto IRAS as part of the review in D2 so that REC & governance reviewers can satisfy themselves that the required changes (and no others) have been made post-CRE review to the sections of the participant information sheet(s) relating to research exposures.</i>		

F3: To be completed by the CRE

In keeping with the MPE assessment:

As part of the study you may receive up to 3 chest X-rays, some of which you would not have had if you did not take part.

X-rays are a form of ionising radiation and are used to create images of your body. The risk of exposure to radiation is that you may develop cancer some years in the future.

1 in 2 people in the UK will develop cancer at some point in their lifetime. Taking part in the study will increase the chance of this happening to you by only a very small amount.

Details of lead CRE (IRAS part B section 3 D3):

Title	Dr
Forename	Rizwan
Surname	Basit
Organisation	Choice Teleradiology
Address	71-75 Shelton Street, London. WC2H 9JQ
Telephone	
Mobile	07751092584
E-mail	r.basit@choiceteleradiology.co.uk
Professional position	Consultant Radiologist
GMC/GDC registration number	6130116

For the purposes of Radiation Assurance only (not to be copied into IRAS):

Lead CRE's HRA registered reviewer number	HRA7486RA
If different to the above, e-mail used for IRAS authorisation	