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 hra.radiationassurance@nhs.net, specifying which areas of the form require additional rows and how many.

Short study title	A study
IRAS project ID	123456
EudraCT number (CTIMPs only)	2018-123456-78
Estimated start date	April 2018
Estimated end date	September 2019
Median length of participation *(how long are participants in the study?)*	The average length of participation is 6 months, though participants may be involved for longer than the time specified based on when they enter the study and how long it takes their disease to progress.
Is this submission a pre-regulatory approval submission to Radiation Assurance or an amendment? *If it is related to an amendment, please provide the sponsor amendment reference as listed on the notice of substantial amendment form*	Pre-regulatory approval submission

Prognosis, median life-expectancy and median time-to-progression	
Age (specify numerically e.g. 21 – 60 years)	18+
Sex	Male and female
Where applicable: Median time to disease progression Median survival times (where relevant) Maximum time in the study	 6 months 2 years 2 years – all participation will end at the end of the study

Does this study involve:	Yes	No
Radiology? *If "Yes", complete part 1*	☒	☐
Radioactive substances? *If "Yes", complete part 2*	☒	☐
Radiotherapy? *If "Yes", complete part 3*	☒	☐
Non-ionising radiation? *If "Yes", complete part 4*	☒	☐

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	Y	N
Do the participant information sheets have a radiation risk statement?* *If yes, please insert below:*	☐	☒

*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

Participant cohort[1]	Procedure[2]	Body part / exam protocol[3]	Frequency / study point[4]	Maximum possible examinations for maximum possible time in study	Maximum examinations for median time in study	Approximate number routine care – including frequency / time points	Reporting & copy images required[5]
N/A	Triple phase CT scan	Chest, abdomen and pelvis as a minimum, plus any other areas where disease is suspected	Screening, then every 8 weeks until disease progression	14	4	2 routine care – conducted every 12 weeks	RECIST v1.1
N/A	CT-guided biopsy (or ultrasound guided biopsy)	Lung	Screening and disease progression	2	2	0	N/A

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	☐	☒

Comments (to include variations between sites):

Notes
[1] e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.
[2] e.g. 'Triple-phase CT scan' not 'CT scan'.
[3] 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.
[4] e.g. 'Baseline, then every 8 weeks'.
[5] e.g. 'RECIST'.

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

Participant cohort[1]	Procedure[2]	Radioactive substance / Radio-pharmaceutical	Body part / exam protocol[3]	Frequency / study point[4]	Maximum possible examinations for maximum possible time in study	Maximum examinations for median time in study	Approximate number routine care –including frequency / time points	Specify any study protocol-specific reporting and / or data processing required?[5]
N/A	Whole body bone scan	TC-99m phosphonates and phosphates	Whole body (head to toe)	Screening, only if clinically indicated	1	1	0	As per local reporting

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 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	☐	☒

Comments (to include variations between sites):

Notes
[1] e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.
[2] 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.
[3] 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.
[4] e.g. 'Baseline, then every 8 weeks'.
[5] e.g. e.g. lesion scoring, SUV analysis, quantification, structured reporting

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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?	☒	☐

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

Details of patients to be studied	
Number (whole study)	60
Age range (specify numerically e.g. 21 – 60 years)	18+
Sex	Male and female
Clinical condition	Lung cancer

	Y	N
Will any of the study participants be healthy volunteers?	☐	☒

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 hra.radiationassurance@nhs.net 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? *Give details of screening procedures and advice to be given to women of child-bearing age* (to be copied into IRAS A3)
Participants who are currently pregnant will be excluded from participating in the study. Female participants will be required to have a pregnancy test every 4 weeks. They will also be required to use two highly effective methods of contraception whilst participating in the study and for a further 60 days after their participation has ended. If a female participant is suspected to be pregnant the principle investigator should be informed immediately. Pregnant participants will be withdrawn from the trial.

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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.

Participant cohort[1]	Procedure[2]	Treatment site and phase	Dose prescription(s), protocol[3]	Technique, protocol[4 or 5]	Dose prescription, routine care[3]	Technique, routine care[4 or 5]	Number of exposures, protocol[6]	Number of exposures, routine care[6]
N/A	Pre-treatment imaging	Radiotherapy planning CT scan of lungs	N/A	3D CT	N/A	3D CT	1	1
N/A	Treatment	Radiotherapy treatment of the lungs	15Gy in 20 fractions over 4 weeks	3D conformal radiotherapy	15Gy in 25 fractions over 5 weeks	3D conformal radiotherapy	20	25
	Please Select:							
	Please Select:							
	Please Select:							
	Please Select:							

	Y	N
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	☐	☒

Comments (to include variations between sites):

Notes

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

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

[3] 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.

[4] e.g. single applied field, electron, 3D conformal, IMRT, volumetric/arc therapy.

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

[6] 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 ima
you should specify the maximum number of exposures.

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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.

Participant cohort[1]	Procedure[2]	Scan extent –body part / exam protocol[3]	Frequency / study point[4]	Maximum possible examinations for maximum possible time in study	Maximum examinations for median time in study	Approximate number routine care – including frequency / time points	Reporting & copy images required[5]
N/A	Ultrasound-guided biopsy (or CT-guided biopsy)	Lung	Screening and disease progression	2	2	0	N/A

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
[1] e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.
[2] e.g. 'Triple-phase CT scan' not 'CT scan'.
[3] 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.
[4] e.g. 'Baseline, then every 8 weeks'.
[5] e.g. 'RECIST'.