**Research Approval Pro-forma for Radiology, Radiotherapy and Cath Labs Procedures**

This form should be completed by the research team and agreed with relevant staff in radiology and radiotherapy and in conjunction with the study Protocol, IRAS form and localised Patient Information Sheets. For further guidance on when and how to complete this form please refer to our pro-forma guidance (on the R&D website) or contact the Research & Development department on 0117 342 0233.

**Section A- Study information**

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| R&D Number:       Study Title:        | Principal Investigator (PI) at UHBW:      Funding arrangements:        |
| **Planned open date agreed with sponsor at this site:**      /     /      | At this site Estimated study end of recruitment date:      /     /     Estimated end of support department involvement date:      /     /      |

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| **Summary Information** |
| Estimated number of participants at this site:      **Any specific reporting requirements for radiology (e.g. RECIST)?** YES [ ]  NO[ ] If yes, please provide details:**Please detail any additional resource issues for the radiology/radiotherapy/cath labs department to consider** (e.g. pre-trial requirements such as training or test scans, case report form completion by radiologists/radiographers etc).      |

**Section B – Procedures to be performed**

1. **Ionising Radiology/Imaging**

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| **Ionising procedures** (full description including anatomical areas, general anaesthetic requirements, which scanner to be used if known) | VisitsWhere more visits are required (i.e. the patient is routinely scanned until disease progression, please make a note in the comments box) | Estimated number of patients requiring General Anaesthetic for procedure and description of requirements (including for example whether bed space needed)  | Comments (including whether radiology or cath labs procedure, whether ARSAC approval required, whether examinations will be performed at other Trusts, e.g. NBT/Alliance) |
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\*Please record all ionising radiology/imaging procedures to be carried out for the protocol, by marking it as RC if part of routine clinical care or X if required in addition to routine clinical care.

To be completed by MPE:

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| Procedure | IRAS value ED (mSv) | IRAS value DAP/DLP/MBq | IRAS using typical or max. doses? | Local typical value ED (mSv) | Local typical value DAP/DLP/MBq | Local max. ED (mSv) | Local max. DAP/DLP/MBq |
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**Notes on any differences between IRAS form part B and local practice** (e.g: Part B will list all potential exposures such as different imagine modalities that can be used - for a biopsy required it could be US/CT/MRI guided. So the IRAS form may include information on a CT guided biopsy, but locally we will only do US guided biopsies, Please note any differences here for the MPE team:

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| Procedure | No. routine care exposures | No. additional / research exposures | Local total ED (local max x total no. exposures) (mSv) | Local trial dose constraint ED (local max x no. additional /research exposures) (mSv)  |
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| **Total** | --- | --- | **---** | **---** |

N.B: The local typical and maximum doses and dose constraint are for standard size patients.

**ARSAC requirements for diagnostic procedures**

**To be completed by MPE**

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| Does the UHBW employer licence cover the procedures required?  |  |
| Are relevant practitioner licences in place at UHBW(list all current licence holders) |  |
| Name of lead practitioner for ARSAC |  |

1. **Non-ionising radiology**

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| **Non- Ionising procedures** (full description including anatomical areas and general anaesthetic requirements) | VisitsWhere more visits are required (i.e. the patient is routinely scanned until disease progression, please make a note in the comments box) | Estimated number of patients requiring general anaesthetic for procedure and description of requirements (including for example whether bed space needed) | Comments |
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\*Please record all non-ionising radiology procedures to be carried out for the protocol, by marking it as RC if part of routine clinical care or X if required in addition to routine clinical care.

1. **Radiotherapy/Radioisotopes Treatment (to include planning and verification imaging)**

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| Radiotherapy/Molecular Radiotherapy Procedure | Description of standard care | Additional requirements for research study | Comments  |
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**ARSAC requirements for therapeutic procedures**

**To be completed by MPE**

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| Does the UHBW employer licence cover the procedures required?  |  |
| Are relevant practitioner licences in place at UHBW (list all current licence holders) |  |
| Name of lead practitioner for ARSAC |  |

**(iv) PACS requirements (i.e. anonymised copy scans)**

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| Imaging procedures requiring copy scans (please separate out imaging areas e.g. CT chest, CT abdomen etc.) | Number required per patient | Frequency (i.e. every 6 months) | Types of copy scans required (include anonymisation requirements and details of when required – e.g. maximum 2 days after scan to confirm eligibility?) | Details of image transfer required e.g. Bolt and a nominated UHBW e-mail address to receive image link, and any applicable timeframes |
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**Section C- Authorisations**

**These authorisations are encouraged to be obtained via email. This pro-forma should be sent to the necessary signatories who should return the pro-forma with an accompanying email confirming authorisation. There is no need to document this agreement on the form. If it is easier to obtain hard copy signatures please complete these below:**

*All ionising radiation procedures require sign off by a Medical Physics Expert and an IRMER practitioner. The MPE should check that an IRMER Nuclear medicine practitioner is prepared to do this study under their ARSAC licence.*

*Note: The IRMER practitioner will be a registered health professional with clinical expertise in the modality involved e.g. radiologist / oncologist / cardiologist / dentist. They are signing to verify that the exposures are justified.*

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|  | Name | Signature | Date |
| *IRMER practitioner authorisation (radiology procedures)*  |  |  |  |
| *IRMER practitioner authorisation (radiotherapy procedures)* |  |  |  |
| *IRMER practitioner authorisation (cath labs procedures)* |  |  |  |
| *Medical Physics Expert authorisation (diagnostic radiology):*  |  |  |  |
| *Medical Physics Expert authorisation (diagnostic nuclear medicine)* |  |  |  |
| *Medical Physics Expert authorisation (therapeutic):*  |  |  |  |

*Authorisation is required for radiology procedures and reporting related to this study and should be completed by the appropriate site-specific radiologist(s).*

*The radiologist is signing to confirm there is capacity for ‘the above standard care’ reporting.*

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|  | Name | Signature | Date |
| *Site Specific Radiologist authorisation:*  |  |  |  |
| *Site Specific Radiologist 2 authorisation (if applicable):*  |  |  |  |

PACS Authorisation is required for capacity of PACS team to fulfil copy scan requests.

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|  | Name | Signature | Date |
| *Head of PACS authorisation* |  |  |  |

***Capacity/resource authorisation***

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| Resource Authorisation | Role | Signature | Date |
| *Radiotherapy* | *Radiotherapy/radioisotopes for all radiotherapy procedures related to the study* | *Radiotherapy Service Manager* |  |  |
| *Radiology* | *Imaging capacity/resource*  | *Head of Service* |  |  |
| *General Anaesthetic* *(if required)* | *GA capacity/resource* | *General Manager (for applicable clinical division)* |  |  |
| *Cath Labs* | *Cath Labs capacity/resource* | *Cath Labs Manager (or Cardiology Research Team Lead if capacity confirmed at Cardiology Research Group)* |  |  |

**For guidance on who the appropriate signatories are please refer to our guidance document which can be found on the R&D website or contact Research and Development on 0117 342 0223**

**Section C – for Radiology to complete post authorisation**

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| **Requirements for each individual procedure request**  |
| **When requesting a procedure, please ensure you include the following details and format:** **Modality:**Name of trial: Disease Group:Clinical Details:Procedure/imaging required:For what date required:Trial mandated requirements:Reporting requirement: Date of comparative scan:  |