Interventional research protocol proforma

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| **Study Name:** |  |
| **Investigators:** |  |
| **Ethics reference:** |  |
| **IRAS project ID:** |  |
| **Sponsor:** |  |
| **Funder:** |  |
| **Date of meeting:** |  |

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| **Study Synopsis**  (please include study design and aims/objectives) |  |

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| **Number of participants:** | |  | |
| **Outline of procedures to be performed per participant:** | |  | |
| **Are any parts of the procedure(s) included as part of routine clinical care?:** | | Yes – (please highlight which ones)  No | |
| **AMIIC drugs required:** | | Midazolam  Fentanyl  Other (please list) | |
| **How will your participants be arriving to AMIIC?:** | | |  |
| **AMIIC clinical team members required:** | | | ☒ Radiographer (AMIIC radiographer will always be required)  Scrub nurse  Circulating nurse  Sedation-trained nurse  Recovery nurse  Physiologist |
| **Additional support required?:** | | | Yes – (please provide details)  No |
| **Recovery time post procedure:** | | |  |
| **Will any participants require overnight admission to the OUH?:** | | | Yes – (please provide details)  No |
| **Will the participant be given sedation or GA?** | | | Yes – (please provide details)  No |
| **Contrast volume required:** (if applicable) | | |  |
| **Maximum permissible Radiation Dose:** (proof of agreed dose in ethics application required) | | |  |
| **Who are the practitioner(s) as defined under IRMER) for this study?:**  (Please see <http://www.e-radiography.net/regsetc/Irmer_people_classification.htm>  for practitioner classification description) | | |  |
| **Who are the operator(s) as defined under IRMER) for this study?:**  (Please see <http://www.e-radiography.net/regsetc/Irmer_people_classification.htm>  for practitioner classification description) | | |  |
| **Image storage required:** | | | PACS  CD – supplied by investigators  Hardrive – supplied by investigators |
| **Is a report required? If so, who will be responsible for this?:** | | |  |
| **Specific days and/or times for procedure:** |  | | |
| **Expected length of time for procedure:** |  | | |
| **Equipment available for the procedure:** | IVUS  Coroventis  Balloon pump  OCT | | |
| **Equipment to be brought in to AMIIC:**  *(Please be aware there is no storage available in AMIIC)* |  | | |

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| **University grant code:** |  | |
| **Contact for funding queries and invoicing:** | Name: | |
| Email: | |
| **Primary contact details for research project:** | Name: |  |
| Email: |  |
| Contact number: |  |
| **Secondary contact details for research project:** | Name: |  |
| Email: |  |
| Contact number: |  |
| *Please ensure that AMIIC is acknowledged on all publications and reference details are passed to the Operations Manager using the following wording:*  *‘We wish to acknowledge the facilities provided by the Acute Multidisciplinary Imaging and Interventional Centre’* | | |

**Please send a copy of the following documents to AMIIC Operations Manager/Lead Research Nurse**

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| --- | --- |
| **Research ethics approval letter** |  |
| **MHRA/HRA approval letter** |  |
| **OUH Trust R & D approval – if applicable** |  |
| **Approved study protocol** |  |
| **SLA for use of AMIIC facilities - any study NOT sponsored by the University of Oxford** |  |

Action points:

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| --- | --- |
|  | Name of attendee: |
| **AMIIC Director** |  |
| **Clinical lead** |  |
| **Nurse** |  |
| **Radiographer** |  |
| **Physiologist** |  |
| **Study investigator** |  |
| **Operations Manager** |  |
| **AMIIC study tag for Medesk use:** |  |
| **Anticipated start date:** |  |