**Research Facilitation Group (C/RFG) Principal Investigator (PI) Questionnaire**

This group reviews the Trusts operational capacity and capability to deliver a study involving UHB patients/staff/facilities/data/samples. Please note that this questionnaire is the responsibility of the Principal Investigator to sign off. If you do not have access to R+D Manager please e-mail the documents to [rfg@uhb.nhs.uk](mailto:rfg@uhb.nhs.uk) or [crfg@uhb.nhs.uk](mailto:crfg@uhb.nhs.uk) and ask that they be uploaded. The team will inform the PI and Team Lead if a face to face presentation is required. Please ensure the following documents are uploaded to the R+D Manager record before requesting a review slot:

* REC/ HRA Approval documents
* Latest Protocol
* Blank patient information (PIS) + consent form
* Completed PI questionnaire
* Funding details i.e. copy of grant application/ award letter if Lead Site and/or Statement of Activities/ Events if participating
* If Pharmacy involvement; IB; Material Safety Data Sheet or Pharmacy Review Sheet Sample IMP Labels
* Manuals (Lab, Pharmacy, Imaging)

**1. Study Details:**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Feasibility Number (F): |  | Click here to enter text. |
|  |  |  |  |
| b) | RRK Reference: |  | Click here to enter text. |
|  |  |  |  |
| c) | Study Acronym: |  | Click here to enter text. |
|  |  |  |  |
| d) | Full Study title: |  | Click here to enter text. |
|  |  |  |  |
| e) | Lead Site or Participating Site: |  | Choose an item. |
|  |  |  |  |
| f) | UHB Principal Investigator: |  | Click here to enter text. |
|  |  |  |  |
| g) | Hospital sites: |  | Choose an item. |
|  |  |  |  |
| h) | Phase of study? |  | Choose an item. |
|  | *If other please state:* |  | Click here to enter text. |
| i) | Version & Date of Protocol: |  | Click here to enter text. |
|  |  |  |  |
| j) | Ethics status: |  | Choose an item. |
|  |  |  |  |
| k) | Sponsor: |  | Click here to enter text. |
|  |  |  |  |
| l) | Funder type: |  | Choose an item. |
| m) | Is this study CRN portfolio adopted? |  | Choose an item. |
|  | *If Yes, please provide CRN number* |  | Click here to enter text. |
|  | *If No/ Rejected; please state reason* |  | Click here to enter text. |
|  |  |  |  |
| n) | Will your study require support from any of the following NIHR infrastructure? |  | ATF  CRF  ATTC  ECMC  BRC  Other (*please detail below*) |
|  |  |  | Click here to enter text. |

**2. Funding: Without confirmation of funding we cannot review and your application will be returned**

a) What funding will UHB receive for the study delivery? Please provide a breakdown of funding to demonstrate the internal distribution of income e.g. Pharmacy/Imaging. This information will be included in subsequent contracts.

|  |  |  |
| --- | --- | --- |
| Department Name | Funding Amount | Funding for/ comments |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

d) Have any cost savings been identified (i.e. to Commissioners/Division) Please detail.

|  |  |  |
| --- | --- | --- |
| Department Name | Funding Amount | Funding for/ comments |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

**3. Delivery:**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Does the study involve patients? |  | Choose an item. |
|  |  |  |  |
| b) | Does the study involve healthy volunteers? |  | Choose an item. |
|  |  |  |  |
| c) | Where do you plan to see your patients? *(Department/ Ward names e.g. CRF, Outpatients etc)* |  | Click here to enter text. |
|  |  |  |  |
| d) | Which Research Team will deliver the study: |  | Click here to enter text. |
|  |  |  |  |
| e) | Have they agreed they have capacity? |  | Choose an item. |
|  |  |  |  |
| f) | Name of Lead Nurse/Lead for team. |  | Click here to enter text. |
|  |  |  |  |
| g) | Intensity Score *(this is completed by the Research Team Lead Nurse)* |  | Validated by:  Click here to enter text. |
|  | Annual whole time equivalent (WTE) |  | Click here to enter text. |
|  | Total/ overall WTE |  | Click here to enter text. |
|  |  |  |  |
| h) | Person responsible for registering patients on PICs and uploading the consent onto UHB portal |  | **Name/ email:**  Click here to enter text. |
|  |  |  |  |
| i) | What type of case report forms will be used e.g. electronic/ paper CRF’s or both? |  | Choose an item. |

**4. Additional Delivery Elements**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Does the study involve multiple arms? |  | Choose an item. |
|  | **IF NO GO TO QUESTION 4F** |  |  |
|  |  |  |  |
| b) | Are patients randomised to a particular arm? |  | Choose an item. |
|  |  |  |  |
| c) | Is randomisation restricted to a particular patient cohort? |  | Choose an item. |
|  | *If yes please detail:* |  | Click here to enter text. |
|  |  |  |  |
| d) | Please list the number of treatment arms: |  | Click here to enter text. |
|  |  |  |  |
| e) | Please detail the treatment/ procedure that is not standard of care: |  | Click here to enter text. |
|  |  |  |  |
| f) | Are there any voluntary sub studies as part of the trial? |  | Choose an item. |
|  | **IF NO GO TO QUESTION 5A** |  |  |
| g) | Do you plan to take part in the sub study? |  | Choose an item. |
|  | *If yes please detail:* |  | Click here to enter text. |
|  |  |  |  |
| h) | Are any significant amendments planned by the Sponsor? |  | Choose an item. |
|  |  |  |  |

**5. Study timelines:**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Predicted opening date: |  | Click here to enter a date. |
|  |  |  |  |
| b) | Proposed SIV:  \*Please note that C/RFG approval is required before Trust approval can be issued |  | Click here to enter a date. |
|  |  |  |  |
| c) | Competitive Recruitment |  | Choose an item. |
|  | *If yes, global target* |  | Click here to enter text. |
|  |  |  |  |
| d) | Local target agreed |  | Per annum: Click here to enter text.  Total: Click here to enter text. |
|  |  |  |  |
| e) | Expected recruitment closure date |  | Click here to enter a date. |
|  |  |  |  |
| f) | Average life expectancy of patient group: |  | Click here to enter text. |

**6. Supervision**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Is the PI substantively employed by UHB |  | Choose an item. |
|  | If no, Supervisor Name: |  | Click here to enter text. |
|  |  |  |  |
| b) | Are there Research Fellows/ or Students involved in delivery? |  | Choose an item. |
|  | Please detail their R&D induction/ training plan  i.e. GCP/ Consent/ PI training |  | Click here to enter text. |

**7. Standard of Care:**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Which hospital are patients usually seen for their visits: |  | Click here to enter text. |
|  |  |  |  |
| b) | Routine treatment for this patient group: |  | Click here to enter text. |
|  |  |  |  |

**8. Pharmacy:**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Is Pharmacy required: |  | Choose an item. |
|  |  |  |  |
| b) | Does the Study involve a CTIMP: |  | Choose an item. |
|  | *\*Please note, even if your study is not a CTIMP there may be a requirement for pharmacy involvement.* |  |  |

**9. Imaging/ Radiology/ Nuclear Medicine:**

\*Please note a *“research exposure” is defined as any exposure required by the research protocol following initial consent from the participant.* It includes all exposures carried out on the participant as determined by the protocol, including those which would otherwise be part of routine clinical care for patients treated outside the research setting.

|  |  |  |  |
| --- | --- | --- | --- |
| Does the study: | |  |  |
| a) | Involve more than one cohort with different procedures/ frequencies/ study points? |  | Choose an item. |
|  |  |  |  |
| b) | Involve more than one Arm with different procedures/ frequencies/ study points? |  | Choose an item. |
|  |  |  |  |
| c) | Involve Radiology? |  | Choose an item. |
|  |  |  |  |
| d) | Involve Radioactive substance/ Radio-pharmaceutical administration? |  | Choose an item. |
|  |  |  |  |
| e) | Involve Radiotherapy? |  | Choose an item. |
|  |  |  |  |
| f) | Does the study involve non-ionising radiation? |  | Choose an item. |
|  |  |  |  |

Please complete Appendix 1 in full if you selected yes to any of these.

**10. Laboratory:**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Where will samples be processed: |  |  |
|  | UHB CLS |  | HGS |
|  | Central Labs |  | UoB |
|  | CRF Lab  *\*SAC approval required* |  |  |
|  |  |  |  |

Please complete Appendix 2 in full if you selected yes to UHB CLS or HGS.

**11. Devices:**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Will any devices be sent to site for the study? |  | Choose an item. |
|  | *If no, go to Q11* |  |  |
|  |  |  |  |
| b) | *UHB Medical Device Form completed?* |  | Choose an item. |
|  |  |  |  |
| c) | Please detail the devices:  *e.g. electronic tablets, diary devices, ECG machine etc.* |  | Click here to enter text. |

**12. Internal feasibility/capacity/portfolio review:**

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Approved by Internal Research Facilitation Group |  | Choose an item. |
|  |  |  |  |
| b) | Name of group and date of approval |  | Click here to enter a date. |
|  |  |  |  |
| c) | PIP Priority number (if applicable) |  | Click here to enter text. |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Form completed by:** |  |  |
|  | Name |  | Click here to enter text. |
|  | Title/ Position |  | Click here to enter text. |
|  | Date |  | Click here to enter a date. |

**Appendix 1 - Imaging/ Radiology/ Nuclear Medicine:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Procedure** | **Yes,**  **No or**  **N/A** | **Anatomical**  **Scope (body**  **part) /views** | **Examinations determined by the protocol, frequency/study time point** | **Examinations for**  **routine care,**  **frequency/time point** |
| CT | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Plain X-ray | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Mammogram | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| DEXA | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Fluoroscopy | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Intervention:  Fresh Tissue Biopsy  (include anatomical area)  and /or Treatment | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| MRI | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| US | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| PETCT | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Bone Scan | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| MUGA | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| GFR | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Other  Radionuclide | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

|  |  |  |  |
| --- | --- | --- | --- |
| a) | Is anonymous imaging/ data transfer to a third party required as part of the trial  ***\*****This may be procedure specific* |  | Choose an item. |
|  |  |  |  |
| b) | Please specify imaging data transfer recipient / method of transfer |  | Click here to enter text. |
|  |  |  |  |
| c) | Is a phantom or volunteer\* scan required as part of the trial  *\*A volunteer scan will require prior approval from a research ethics committee*  (MHRA MRI Safety Guidelines) |  | Choose an item. |
|  |  |  |  |
|  |  |  |  |
| d) | Is QA/QC\* required as part of the trial  *\*Guidelines will be required* |  | Choose an item. |
|  |  |  |  |
| e) | Is study specific reporting criteria required?  *e.g. RECIST, RANO* |  | Choose an item. |
|  |  |  |  |
| f) | Name of Consultant Radiologist and/or Practitioner License ID (for Radionuclide  administration) contacted for study support |  | Click here to enter text. |

**Appendix 2 - Laboratory**

**For UHB/ HGS labs support please complete the following:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test | Volume | Type | Frequency | Total per patient | Estimate total for trial |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

|  |  |  |  |
| --- | --- | --- | --- |
| c) | Estimate number of patients to be screened |  | Click here to enter text. |
|  |  |  |  |
| e) | Please confirm funding for test |  | Click here to enter text. |
|  |  |  |  |
| f) | Who (if anyone) has confirmed lab support |  | Click here to enter text. |
|  |  |  |  |
| g) | Will any test precede treatment |  | Choose an item. |
|  | *Please detail if yes:* |  | Click here to enter text. |
|  |  |  |  |
| h) | Is specialist processing required |  | Choose an item. |
|  | *Please detail if yes:* |  | Click here to enter text. |
|  |  |  |  |
| i) | Are there any specific preparation and storage requirements from UHB CSL |  | Choose an item. |
|  | *Please detail if yes:* |  | Click here to enter text. |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |