kch_ft_colour

**Feasibility Checklist**

To be used for the departmental feasibility review of new studies. Please answer all questions below. All forms should be reviewed by a Research Facilitator before authorisation by the PI and R&I Lead.

**Date of completion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study Title:** | |  | | | | | | |
| **Short Title/Acronym:** | |  | | | | | | |
| **Sponsor Institution:** | |  | | | | | | |
| **Funder:** | |  | | | | | | |
| **IRAS number:** | |  | | | | | | |
| **Chief Investigator:** | |  | | | | | | |
| **NIHR CRN Portfolio Status:** | | Intending to apply for adoption/Portfolio Adoption confirmed  Non-portfolio/not eligible | | | | | | |
| **KCH Principal Investigator:** | |  | | | | | | |
| **KCH Research Delivery Unit:**  (Location within KCH that will take responsibility for the study) | |  | | | **KCH Research Delivery Sub-Unit** (where applicable) | |  | |
| **Educational study?**  **Yes** | | **University:**  **Academic supervisors:**  **Course/qualification:** | | | | | | |
| **KCH Location: (Check Box)** | **Denmark Hill** |  | **Orpington** |  | | **PRUH** | |  |
|  | **Beckenham Beacon** |  | **Queen Mary’s, Sidcup** |  | |  | |  |
| **SYNOPSIS:** *Provide a brief 1-2 paragraphs* ***lay summary overview*** *of the project* | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. RECRUITMENT:** | | | | | | | | | | | | | | |
| a) How many participants do you aim to recruit at KCH sites?  *(Add total to boxes on right Please do not enter a range, but the maximum number you intend to recruit which will be entered into the study agreement, where applicable)* | | | Denmark Hill: | | | Orpington: | | | PRUH: | | | Beckenham: | | Queen Mary’s: |
|  | | |  | | |  | | |  | |  |
| b) How many patients per month do you need to recruit at each site to meet your target? | | | Denmark Hill: | | | Orpington: | | | PRUH: | | Beckenham: | | | Queen Mary’s: |
|  | | |  | | |  | |  | | |  |
| c) How was this recruitment target calculated? | | |  | | | | | | | | | | | |
| d) How many patients do you expect to have to screen in order to reach the recruitment target? | | |  | | | | | | | | | | | |
| e) Do you have the study population as per the inclusion criteria?  *(How many potential participants are currently seen? Are there sufficient potential participants to meet the requirements of the study?).* | | |  | | | | | | | | | | | |
| f) Is the cohort under the PIs clinical care? If not please identify where/how you will recruit, and whose care the cohort is under. | | |  | | | | | | | | | | | |
| g) How will you ensure to recruit the target within the time period stated? | | |  | | | | | | | | | | | |
| h) Are there any competing studies currently recruiting at KCH?  *(If so, please name them and give the IRAS reference. How will you manage this?).* | | |  | | | | | | | | | | | |
| i) Will the protocol be integrated with routine care?  *(Describe arrangements).* | | |  | | | | | | | | | | | |
| j) How acceptable and attractive to patients is this study likely to be? (E.g. burden vs. benefit to participation).  *(Please explain).* | | |  | | | | | | | | | | | |
| k) How will participants be recruited?  *(Explain logistics of how you will screen and approach eligible patients).* | | |  | | | | | | | | | | | |
| l) How soon following KCH confirmation of Capacity & Capability can you recruit the first participant? How will you prepare for this?  *(All clinical trials will be required to meet the national 70 day benchmark. Please discuss this with your research facilitator).* | | |  | | | | | | | | | | | |
| **2. STUDY CONDUCT** | | | | | | | | | | | | | | |
| a) Where will the research take place within KCH?  *(Please detail all areas, such as CRF, Clinics and Wards and any peripheral clinics / locations external to the Trust).* | | |  | | | | | | | | | | | |
| b) Where will consent take place within KCH?  *(Please detail all areas, such as CRF, Clinics and Wards).* | | |  | | | | | | | | | | | |
| c) Please confirm the Support departments that will be involved in this study at KCH and who will need to provide their approvals: | | | | | | | | | | | | | | |
| N/A No Support Department involvement | | | | | | | | | | | | | | |
| ***Support Department*** | | ***Involved in the study?*** | | | ***If yes, have you already discussed the study?*** | | | | | ***If yes, please provide Name and Email address of contact:*** | | | | |
| Viapath | | Yes  No | | | Yes  No | | | | |  | | | | |
| Radiology | | Yes  No | | | Yes  No | | | | |  | | | | |
| Pharmacy | | Yes  No | | | Yes  No | | | | |  | | | | |
| Cardiology | | Yes  No | | | Yes  No | | | | |  | | | | |
| Neuro Radiology | | Yes  No | | | Yes  No | | | | |  | | | | |
| Clinical Research Facility | | Yes  No | | | Yes  No | | | | |  | | | | |
| Liver Histopathology | | Yes  No | | | Yes  No | | | | |  | | | | |
| Medical Equipment Management Service (MEMS) **for device studies** | | Yes  No | | | Yes  No | | | | |  | | | | |
| Other (Please specify) ……………………………………… | | Yes  No | | | Yes  No | | | | |  | | | | |
| **3. PI & RESEARCH TEAM:** | | | | | | | | | | | | | | |
| a) Does the PI have appropriate experience (e.g. previously been a PI?) | | | | Tick all that apply  Yes, PI has previous experience  Yes, PI has had recent GCP training (within 2 years)  GCP date: \_ \_ / \_ \_ \_ / \_ \_  No – For first time PI’s, please identify a named mentor with PI experience to support  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  For **KCH-Sponsored CTIMP** studies only  Has the Chief Investigator had recent CI training from the KHPCTO?  Yes  No – Please contact the KHPCTO to arrange a 1:1 training. | | | | | | | | | | |
| b) What WTE will the PI allocate to this study?  *(Prospective PI’s with limited research time in their job plans should agree with the Clinical R&I Lead to take on these responsibilities over and above their regular work).* | | | |  | | | | | | | | | | |
| c) Does the PI or any other member of the site have any direct personal involvement *(e.g. financial, share-holding, personal relationship etc. in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?* | | | | Yes  Please detail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No | | | | | | | | | | |
| d) Does the PI have previous experience in meeting recruitment metrics?  *(Provide details).* | | | | Yes  Please reference study IRAS or KCH R&I numbers:­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No | | | | | | | | | | |
| e) Are there specific competencies/training requirements for the study team?  *(Who are these for? Have they been undertaken, or are they pending?).* | | | |  | | | | | | | | | | |
| f) Who will take responsibility for ensuring the research team are suitably resourced and trained to comply with GCP, study specific equipment, CRF completion and any study procedures as per the protocol?  *(This may be delegated by the PI)* | | | |  | | | | | | | | | | |
| f) Who is undertaking the primary work on the study? Please add additional rows if required. | | | | | | | | | | | | | | |
| **Role**  *(i.e. Research Nurse, Trial Coordinator, Data Manager, Research Fellow, Other)* | **Name** | | | | | | | Employer | | | | | Funded by NIHR Clinical Research Network? | If not KCH staff, Will a Research Passport/Letter of Access be required? |
|  |  | | | | | | |  | | | | | Yes  No |  |
|  |  | | | | | | |  | | | | | Yes  No |  |
|  |  | | | | | | |  | | | | | Yes  No |  |
|  |  | | | | | | |  | | | | | Yes  No |  |
|  |  | | | | | | |  | | | | | Yes  No |  |
|  |  | | | | | | |  | | | | | Yes  No |  |
|  |  | | | | | | |  | | | | | Yes  No |  |
| g) What is the study duration and will the identified staff be available for the entirety? | Duration:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Staff availability:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | |
| g) Will any work take place out of hours? If so, what and by whom? | Yes: Please detail the work and who will undertake:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No | | | | | | | | | | | | | |
| h) Will there be any lone working? If so, what policies will be followed? | Yes  Please detail what policies will be followed:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No | | | | | | | | | | | | | |
| i) From the 1st April 2016 – it will be a Trust requirement for ALL research study recruitments (for portfolio and non-portfolio) to be entered weekly on to EDGE. This is the Local Patient Management System commissioned by South London CRN.  Each user will be given **Clinical Access**  This allows access to individual patient information, accrual uploads, access to study documents and data in a read-only format.  Please expand to add additional access requests as required. | Please confirm the name, email address & role for each member of the research team who will require access for this study.  For first time users, a username will be created. For existing users, the EDGE coordinator will link the user to allow access to this study. | | | | | | | | | | | | | |
| **\*PRIMARY EDGE USER RESPONSIBLE FOR EDGE UPLOADS\***  Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Role \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Existing user  New user | | | | | | | | | | | | | |
| Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Role \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Existing user  New user | | | | | | | | | | | | | |
| Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Role \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Existing user  New user | | | | | | | | | | | | | |
| Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Role \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Existing user  New user | | | | | | | | | | | | | |
| Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Role \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Existing user  New user | | | | | | | | | | | | | |
| **4. DATA MANAGEMENT AND EQUIPMENT:** | | | | | | | | | | | | | | |
| a) Where will you store the Investigator Site File?  What are the security arrangements? | | | | | | |  | | | | | | | |
| b) Where will you store any equipment / materials / kits? Is there sufficient space for the duration of the study? | | | | | | |  | | | | | | | |
| c) Are you collecting and storing data on paper? If so, where will you store records and what are the security arrangements? | | | | | | | Yes  Please detail location and security arrangements: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No | | | | | | | |
| d) Are you collecting and storing data electronically? If so, where will you store records?  *(Describe security arrangements).* | | | | | | | Yes  Please detail location and security arrangements: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No | | | | | | | |
| e) For studies requiring IT based activities, are there provisions in place to allow access? E.g. for eCRF completion and IWRS. | | | | | | | Yes  No | | | | | | | |
| f) What are the arrangements for archiving after the end of the study period?  (It is good practice to archive all studies in a long term secure storage facility. However, this is only mandatory for CTIMPs, studies of medical devices and combined CTIMP/device studies. For all other studies, if suitable facilities exist (lockable, fireproof filing cabinet in secure room) then study files can be archived within the research division). | | | | | | | Study is a CTIMP/Device/combined CTIMP & device and will be archived in an off-site archiving facility- (Iron Mountain)  Study is not a CTIMP/Device/combined CTIMP & device but will be archived in an off-site archiving facility- (Iron Mountain) (encouraged for all studies where possible, where funding allows )  Study is not a CTIMP/Device/combined CTIMP & device therefore off-site archiving is not mandatory , study can be archived within suitable facility within the research division | | | | | | | |
| **5. REGULATORY ASPECTS:** | | | | | | | | | | | | | | |
| a) Is MHRA approval required? | | | MHRA CTIMP  MHRA Device  No | | | | | | | | | | | |
| b) Is this a clinical trial involving gene therapy? | | | Yes, GTAC required  No | | | | | | | | | | | |
| c) Are there specific requirements i.e. working with children or incapacitated adults?  *(What extra measures are in place to undertake with this?).* | | |  | | | | | | | | | | | |
| d) Does the study involve ionising radiation or radioactive substances (IRMER/ARSAC)? | | | IRMER  Yes  No  ARSAC  Yes  No  For ARSAC, has contact been made with the Medical Physics Dept?  Yes  No | | | | | | | | | | | |

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| **6. TISSUE** For studies involving tissue  N/A no tissue involved  N/A routine tissue only | | | | |
| Tissue type e.g. whole blood, plasma urine, saliva, biopsy etc. | 1) | 2) | 3) | 4) |
| Tissue source | New  Existing | New  Existing | New  Existing | New  Existing |
| Where will the research samples be processed? |  |  |  |  |
| Will research samples be stored or destroyed after analysis? | Stored  Destroyed | Stored  Destroyed | Stored  Destroyed | Stored  Destroyed |
| Will any tissue be stored for > 7 days? | Yes  No | Yes  No | Yes  No | Yes  No |
| If stored within KCH, what is the unique storage location number |  |  |  |  |
| Who is the person responsible for storage at KCH? |  |  |  |  |
| What is the estimated total number of samples collected and stored? |  |  |  |  |
| Will any samples be imported to KCH for storage? | Yes  No | Yes  No | Yes  No | Yes  No |
| If yes, what is the unique storage location number? |  |  |  |  |
| Will any samples be transferred out of the Trust? | Yes  No | Yes  No | Yes  No | Yes  No |
| If yes, where will the tissue be transferred to? |  |  |  |  |
| What will happen to the samples at the end of the research? | Transfer to a RTB  Storage by research team pending ethical approval for use in another project  Storage by research team as part of a new RTB  Storage by research team of biological material which is not ‘relevant material’  Disposal in accordance to HTA  Not yet known | Transfer to a RTB  Storage by research team pending ethical approval for use in another project  Storage by research team as part of a new RTB  Storage by research team of biological material which is not ‘relevant material’  Disposal in accordance to HTA  Not yet known | Transfer to a RTB  Storage by research team pending ethical approval for use in another project  Storage by research team as part of a new RTB  Storage by research team of biological material which is not ‘relevant material’  Disposal in accordance to HTA  Not yet known | Transfer to a RTB  Storage by research team pending ethical approval for use in another project  Storage by research team as part of a new RTB  Storage by research team of biological material which is not ‘relevant material’  Disposal in accordance to HTA  Not yet known |

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| **7. PAYMENT & FUNDING:** | |
| This section should be completed to confirm the funding arrangements for this study. | |
| a) Will KCH receive any funding in order to conduct this study? | **Yes: KCH will receive funding to conduct the study**  *Please complete section b) below*  **No funding provided by the sponsor**  *If no, please confirm how the costs of the study will be met*  NIHR Portfolio Study, Research Activities covered by CRN funded staff  Costs Funded by PI Research Account, Cost code\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other, please describe­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| b) What funding will KCH receive in order to conduct the study? | **Study costs covered by a grant held by KCH**  *If yes, please confirm grant details below and ensure award letter is submitted:*  Grant Value:­­­­­­­­­­£\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Funder\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Study costs covered by a grant held at KCL**  *If yes, please confirm grant details below and ensure award letter is submitted:*  Grant Value:­­­­­­­­­­£\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Funder\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Study costs covered by the sponsor:**    Per patient payment £\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Archiving fee £\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  One off fee £\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_  Pharmacy fee £\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_  Other £\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_ |
| b) Will KCH receive any drug or consumables for this study free of charge? | **Drug**  If Yes: Please detail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Supplies/Consumables (including medical devices)**  If Yes: Please detail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| c) Are there any Excess Treatment costs (ETCs) associated with this study?  *(Compared with current care, how much of a cost deficit would the potential treatment cost and how will this be covered?) If you’re unsure about whether there are ETCs associated with this study please contact your facilitator.* |  |
| f) For CTIMP studies only:  *(Is an exit strategy in place to cover the costs of CTIMP after the end of the study? )* |  |
| **8. PEER REVIEW:** | |
| a) Has the study been independently peer reviewed?  *(In order for studies to be accepted onto the NIHR portfolio, studies must have received independent peer review)* | Yes – As part of a funding award application  Yes – By an academic supervisor (for student studies only)  No  ***If ‘No’ your facilitator will advise on the KCH R&I requirement for peer review.*** |

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| **OUTCOME OF FEASIBILITY REVIEW** |
| **KCH PI Details:**  **Name of PI (Please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Statement:** I agree to adhere to the HRA approved protocol, patient consent, Information Governance, Human Tissue Act and Mental Capacity Act arrangements (where applicable).  **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_\_\_** |
| **Reviewer Details (*if applicable*):**  **Name of Academic Supervisor (Please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_\_\_** |
| **Reviewer Details:**  **Name of R&I Lead/RGB Chair (Please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_\_\_** |