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**Guidelines for the development of a UoB Clinical Trials Unit trial with a Birmingham Health Partner NHS Trust**

These guidelines have been developed to facilitate the efficient development of clinical trials that are led by a UoB Clinical Trials Unit and have a Birmingham Health Partner NHS Trust as a lead clinical site. The aim of the guidelines are to reduce delays that can be encountered when determining the costings required for a clinical trial grant submission and ultimately be able to deliver the trial within the NHS.

**Defining the projects which fall under this guideline:**

1. A Birmingham Health Partner (BHP)-based Investigator wishing to develop an investigator-led clinical trial with a UoB Clinical Trials Unit (CTU) involving a BHP NHS Trust as the lead site.

**Steps for development of a funding application:**

1. A BHP Investigator wishing to develop a ‘investigator-led clinical trial’ with a UoB CTU needs to contact the CTU at the earliest opportunity via the UoB CTU New Business process. Any investigator contacting the NHS partner directly about a project which falls under this guideline will be re-directed to the CTU via this route for support. See Appendix 1 for contact details.
2. Investigator contact with the CTU will be initiated by the completion of a New Business Request form and the UoB CTU New Business process will be followed. See Appendix 1 for New Business Request form.
3. Upon CTU acceptance of the proposal for development, a CTU representative will email the lead Trust a copy of the CTU New Business Request form (UHB – RAS@uhb.nhs.uk, BWCH - Bwc.research@nhs.net)

The email should contain the following information

* Title of email – lead NHS trust support
* Funder, expected scheme and grant deadline
* CI name and contact details
* Completed CTU New Business Request form
* Name of proposed sponsor
1. The BHP NHS Partner will undertake initial review and will then indicate if they provide ‘support in principle’ of the grant application.
2. The CTU will work with the Investigator to develop the trial and funding application.
3. As soon as possible, the CTU will provide a trial synopsis and preliminary list of all expected investigations/procedures to the Trust on the Costing template, by using the Schedule of Events Cost Attribution Tool (SoECAT, via the link: <https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/excess-treatment-costs.htm> ). Investigators are advised not to obtain costs independently.
4. The Trust R&D will verify if all investigations/procedures are routine within 5 working days of receipt of synopsis and costing template. This will be for the basic level investigation unless otherwise specified and is subject to final agreement (step 8).

The CTU will be notified by the Trust R&D if any non-routine investigations/procedures that require further referral to NHS and will take longer than 5 working days.

If queries are raised by the Trust R&D on specific investigations, the CTU must respond within 5 working days.”

1. Upon grant award the UoB CTU will inform the BHP NHS Trust of the outcome via email. Any changes to the design and budget impacting the NHS Trust, requested by the funder or in response to reviewers comments, will be discussed and agreed prior to response to the funder.
2. Award accepted and award set up process initiated.

New Business Proposal Form

Name of Chief Investigator (CI):

Department:

Organisation:

Work telephone number of CI:

Work email address of CI:

Have you spoken to any staff at BCTU No [ ]  Yes [ ]

 CRCTU No [ ]  Yes [ ]

**If yes, please provide their name(s):**

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| --- |
| **Working title and/or acronym:**  |

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| --- |
| **Disease area (max. 100 characters):**  |

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| --- |
| **Concept/research question to be addressed (max. 150 words):**  |

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| --- |
| **Brief background/justification (max. 300 words):**  |

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| --- |
| **Planned intervention or treatment arms:**  |

Are you working to a specific deadline: No [ ]  Yes [ ]

If yes, please state; Date:

 Name of funder:

Commissioned call ref (if applicable):

**Is this a Fellowship application:** No [ ]  Yes [ ]

**Has the proposal been discussed by a national or regional independent group?**

 No [ ]  Yes [ ]

If yes, please tick the appropriate group and attach proof of approval:

Birmingham NIHR BRC [ ]  IMPACT [ ]

Cancer NIHR Clinical Study Group (CSG) [ ]  TAP [ ]

Other:

**Please attach any other appropriate supporting documentation.**