# Purpose:

This document provides a template cover letter to use to contact prospective peer reviewer(s) when requesting a peer review on a trial proposal, and a report template for the peer reviewer(s) to complete and return following the review.

# Instructions:

## Cover letter

1. Create a cover letter using the following suggested introductory text or similar:
* All clinical trial protocols require appropriate peer review. It is one of the responsibilities of a research sponsor as defined in the UK Policy Framework for Health and Social Care Research *<version and date as appropriate to sponsors’ country>* to ensure that an appropriate process of independent expert review has demonstrated the research proposal to be worthwhile, of high scientific quality and good value for money. Peer review is the assessment of a research protocol by reviewers who are experts in the relevant field related to the protocol. Reviewers are able to offer independent advice on the scientific validity of the study
1. Also include the following:
* The invite to perform the review
* The basis on which the reviewer was selected
* Reference to the Report Template
* The deadline for return

## Report

1. The Peer Review Report Template, to be completed by the peer reviewer(s) is set up in the section below, and can be made ready for use by:
* Deleting this section.
* Updating the header/footer
* Updating the trial and sponsor names where applicable

# Related documents:

* UoB-CRT-PRV-SOP-001 Peer Review

Thank you for agreeing to undertake a peer review of this project, please ensure ALL sections are completed.

### Chief Investigator:

Project Title:

**Does the clinical trial address a clear research question?**

[ ]  YES - satisfactory [ ]  NO – requires improvement (please comment below)

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**Does the background information adequately justify the clinical trial?**

[ ]  YES - satisfactory [ ]  NO – please comment below

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**Is the methodology appropriate for the clinical trial?**

[ ]  YES [ ]  NO – please explain below

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**Is the proposed sample size sufficient to answer the research question?**

[ ]  YES [ ]  NO – please suggest improvements below

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**Is the importance to the NHS and service users clear?**

[ ]  YES [ ]  NO – please comment below

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**Are the risks associated with the clinical trial justified by the potential for benefit?**

[ ]  YES [ ]  NO – please comment below

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**Given the current proposal, is the clinical trial feasible and achievable (able to answer the research question)?**

[ ]  Very likely

[ ]  Probably – please explain concerns below

[ ]  Not likely – please offer advice below

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**Have risks to participants been appropriately identified and managed within the proposed clinical trial?**

[ ]  YES [ ]  NO – please comment below

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**Any other comments you wish to make about the study?**

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**Declaration**

I declare that I have not been involved in the design of this trial, am not part of the trial team, have read and reviewed the trial proposal/protocol and that I have no conflict of interest in acting as a referee.

For Clinical Trials with commercial funding, insert into section 8.

The <TRIAL> trial protocol is commercial-in-confidence. The recipient of the protocol agrees to hold all information presented within as confidential and agree not to use or disclose, or allow to use or disclosure of the said information to unauthorised parties, directly or indirectly, irrespective of the recommendation regarding the protocol or at any time before, during or after the peer review form has been submitted to the sponsor, without prior written consent.

Signature: ………………………………………………………………………………………………… Date: ………………………….

Print Name: ………………………………………………………………………………………………..

Post held: ………………………………………………………………………………………………..

\* Please return this review to the <Sponsor> Office.