

Canadian Cancer Clinical Trials Network Facilitated External Peer Review Process Reviewer Guidelines

The Canadian Cancer Clinical Trials Network (3CTN) supports a portfolio of academic clinical trials reflecting the priorities of clinicians, researchers, patients, ministries of health and funders. To be eligible for inclusion into the portfolio, a trial must meet all defined eligibility criteria (*see Portfolio Eligibility Criteria and Guidelines for full details*), which includes undergoing peer review (PR) by external reviewers. If a trial being considered for inclusion on the 3CTN Portfolio has not already undergone an acceptable peer review process (*see 3CTN Peer Review Guidelines for full details*), the applicant may contact the 3CTN Coordinating Centre to initiate this 3CTN facilitated PR process.

Please Note: for 3CTN facilitated PR, selected reviewers must be external to the trial being reviewed and non-conflicted. A conflicted reviewer, for the purposes of this process is defined as, but is not limited to:

- A collaborator in the proposed study or a regular collaborator with the Principal Investigator in previous studies;
- Someone involved in the preparation of the study protocol;
- Having a close personal or business relationship with the Principal Investigator;
- Someone from the same institution as the Principal Investigator.

As part of the overall process (*see Appendix A*), two independent peer reviewers will be selected by the 3CTN Coordinating Centre to perform external PR on the study to be considered for Portfolio inclusion. This document outlines the role of independent external peer reviewer for the purposes of including the trial in question on the 3CTN Portfolio of academic trials. The selected external reviewers (*as per Step 4 in Appendix A*) will be required to follow these steps:

1. Review/Sign off of 3CTN Confidentiality of Information Policy

Any study related documents (study protocol, etc) forwarded to reviewers for the purposes of this review will be treated as confidential information and as per the 3CTN Confidentiality of Information (CI) Policy. The assigned external reviewers will be asked to read and sign off on the 3CTN CI policy, if they have not already done so within the past year.

2. Complete the Peer Reviewer Package

The selected reviewers will be sent the following documents:

a) *Review the Reviewer Guidelines*

To ensure consistency and transparency of the 3CTN PR process, reviewers will be provided with this guideline document.

b) *Full Study Protocol*

To ensure the reviewers have the necessary information to review the trial, the study protocol will be provided. On a project by project basis, more documents may be sent to the reviewer if necessary to conduct an adequate review.

c) *Reviewer Form*

This form will be completed to provide 3CTN with the necessary information to assess if the PR criteria can be satisfied for the purposes of including the trial in question on the 3CTN Portfolio of academic trials. The selected box in 'Section 4' of the reviewer form is the overall impression of the study that will be used to



determine whether the PR criteria is satisfied for the study in question. Any of the following three choices will result in the study passing PR: 1) Innovative/excellent trial; 2) Competitive trial; 3) Acceptable trial, whereas selecting one of the following choices will result in the study failing PR: 1) Trial redesign required; 2) Seriously flawed trial

3. Results of the Review

3CTN will receive and review a total of two reviewer forms as a result of the facilitated PR process. The potential results and implications of the results are summarized in Table 1.

Table 1. Potential external peer review outcomes

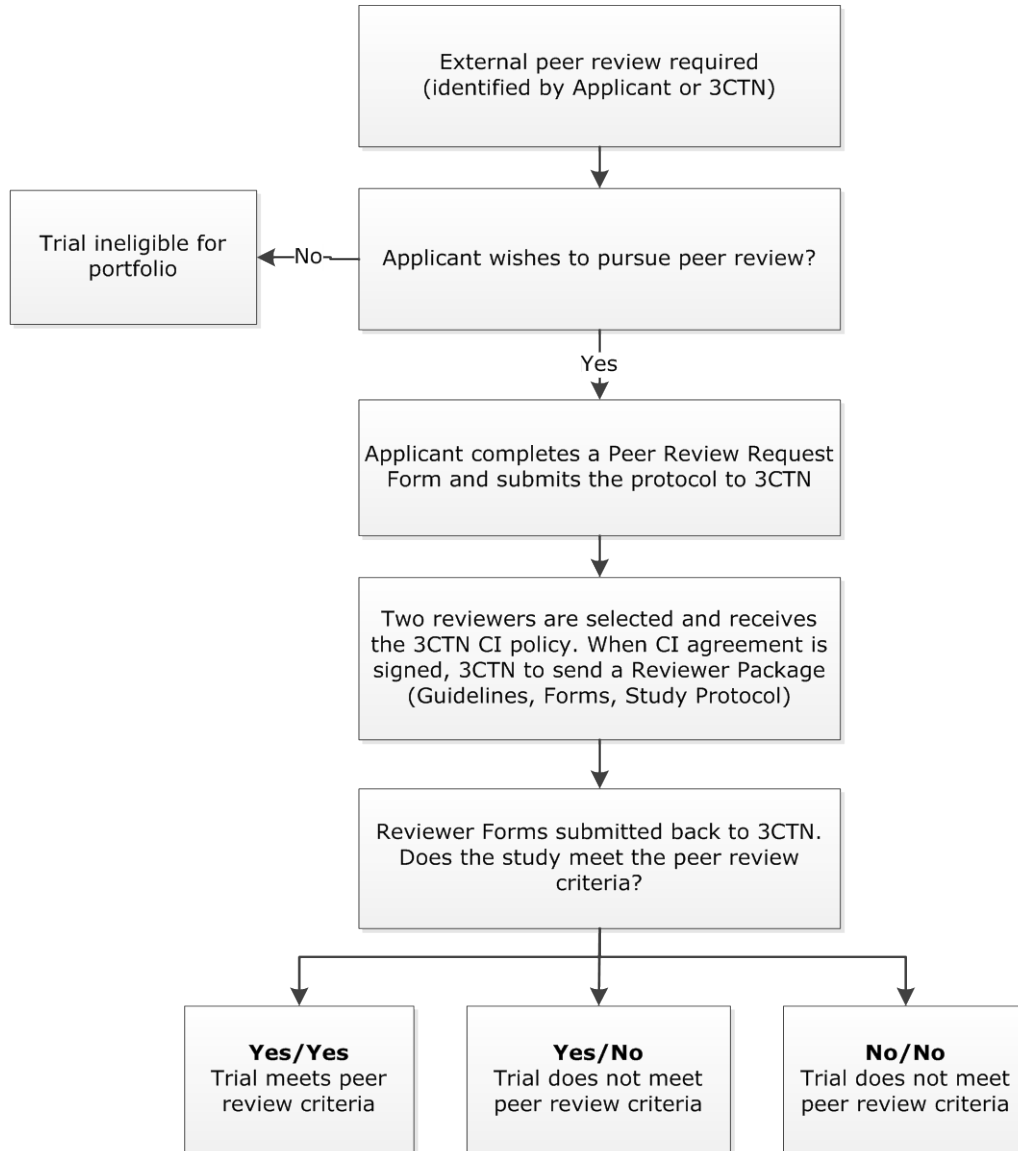
<i>Is the Study of sufficient scientific quality & merit to pass peer review?</i>		
Reviewer A	Reviewer B	Outcomes
Yes	Yes	Trial meets the peer review criteria and is eligible for the 3CTN Portfolio
No	Yes	*Trial does not satisfy the peer review criteria
No	No	*Trial does not satisfy the peer review criteria

*Either of these outcomes will deem the trial ineligible for the 3CTN Portfolio

4. Communication of Results

The final results of the PR process and the anonymized Reviewer Forms will be sent back to the applicant. Please forward the completed “Reviewer Form” to the Manager, Operations at the 3CTN Coordinating Centre. Reviewers are requested to return the completed forms within 14 calendar days.

Appendix A: External Peer Review Process Flow Chart





Document Revision History

Version	Date	Description
1.0	04/27/2015	Draft
2.0	06/26/2015	Final document for publishing (approved by 3CTN Steering Committee)