

Canadian Cancer Clinical Trials Network Facilitated External Peer Review Process 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.

This document outlines the process for an applicant to initiate a 3CTN facilitated independent external PR for the purposes of trial inclusion into the 3CTN Portfolio of academic trials. The process overview is summarized in Appendix A.

1. Request for Peer Review

If the applicant wishes to pursue Peer Review via the 3CTN facilitated PR process, the applicant must complete and submit to info@3ctn.ca:

a) PR Request Form

The PR Request Form includes:

- Applicant contact information;
- Project title;
- Principal Investigator name;
- Five potential non-conflicted external reviewers (*see Section 2.0 for the definition of a conflicted reviewer*).

b) Full Study Protocol

To ensure the reviewers have the necessary information to review the trial, the applicant must submit the study protocol. The study protocol will be treated as a confidential document as per the 3CTN Confidentiality of Information (CI) Policy and will only be used for the purposes of this PR process. 3CTN will also ensure the assigned external reviewers read and sign off on the 3CTN CI policy.

2. Selection of External Reviewers

The Manager, Operations will select two independent external reviewers with the required knowledge, and without conflicts, to review the study protocol and report on the scientific merit and feasibility of the study. The selected reviewers are not limited to the reviewers identified on the PR Request Form.

A conflicted reviewer is defined as:

- 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 at the same institution as the Principal Investigator.

The Manager, Operations will send the 3CTN CI Policy to the assigned external reviewers. The reviewers must review and attest to abiding by the CI Policy and sign an agreement with 3CTN prior to receiving the review package.



3. Review Package

A review package will be sent to each reviewer and will consist of:

- Reviewer Guidelines;
- Reviewer Form;
- Study Protocol;
- Other submitted documentation (if required, on a per project basis).

The reviewers will review the study documentation and complete the Reviewer Form and submit back to 3CTN for internal review within a target timeline of 14 calendar days.

4. Results of the Review

3CTN will review each completed Reviewer Form. The potential results of the review are summarized in Table 1.

Table 1. Potential peer review outcomes

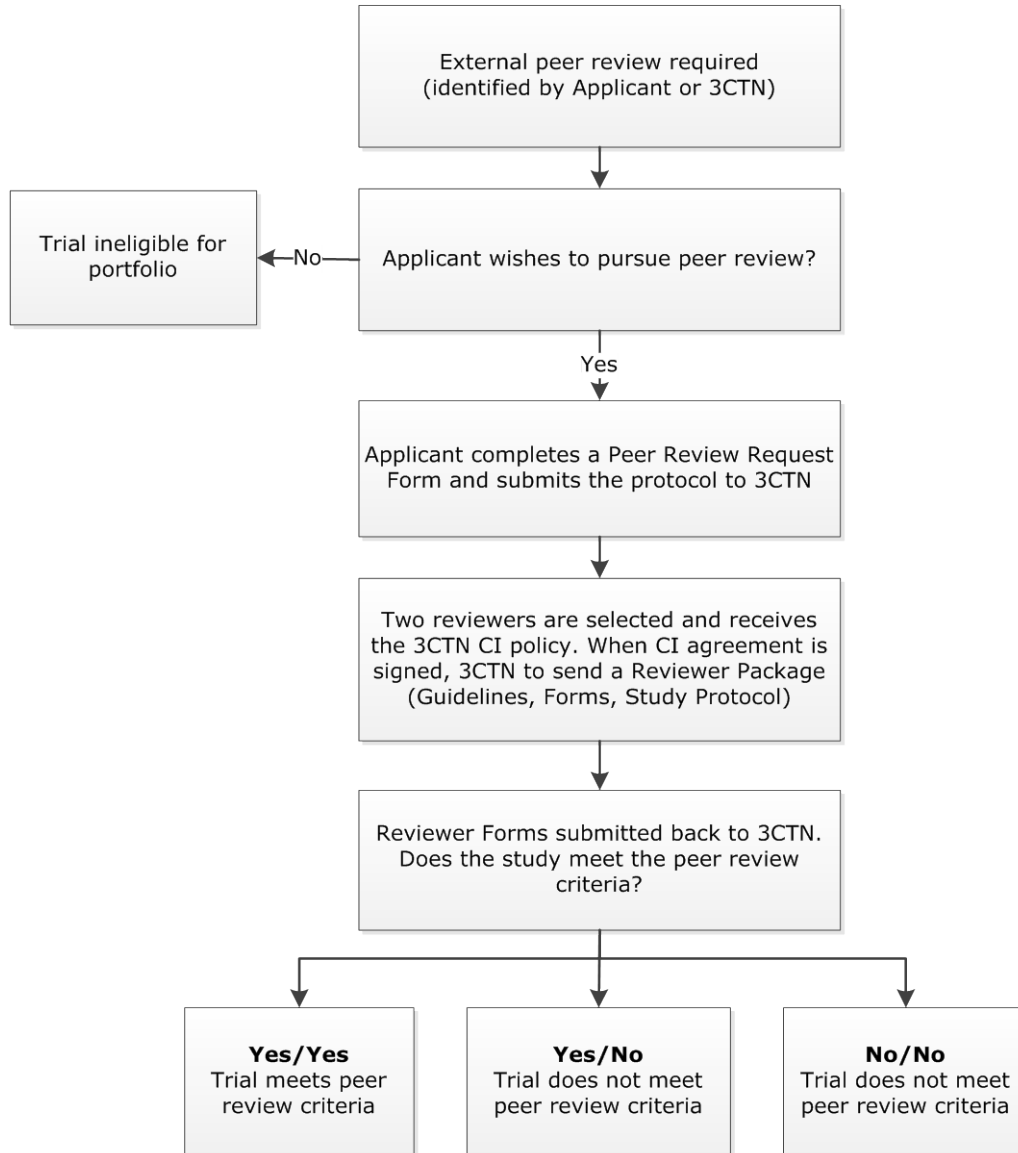
| <i>Is the Study of sufficient scientific quality & merit to pass peer review?</i> | | |
|--|-------------------|---|
| Reviewer A | Reviewer B | Outcomes |
| Yes | Yes | Trial meets the peer review criteria and is eligible for the 3CTN Portfolio |
| No | Yes | *Trial does not satisfy the peer review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

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

5. Communication of Results

The final results of the PR process and the anonymized Reviewer Forms will be sent back to the applicant. Any questions or concerns related to the results or comments on the Reviewer Form should be directed to the Manager, Operations at the 3CTN Coordinating Centre.

Appendix A: 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) |