



## 3CTN Facilitated External Peer Review Process Guidelines

The Canadian Cancer Clinical Trials Network (3CTN) supports a portfolio of academic cancer 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.

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 a Portfolio application form and submit the following to [info@3ctn.ca](mailto: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

This will ensure the reviewers have the necessary information to review the trial. 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.

### 2. Selection of External Reviewers

3CTN 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 3CTN CI Policy will be sent to each assigned external reviewer. The reviewers must review and attest to abiding by the CI Policy and sign a confidentiality form with 3CTN prior to receiving the review package.

The deadline to complete the facilitated peer review process (FPR) is 8 weeks. The application will be closed until Applicant notifies 3CTN that FPR can resume.



**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).

Completed Reviewer Forms will be submitted back to 3CTN for internal review within 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 &amp; merit to pass peer review?</i> |                   |  |
|---|-------------------|--|
| <b>Reviewer A</b>   | <b>Reviewer B</b> | <b>Outcomes</b>  |
| 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. Under the guidance of the Portfolio Sub-Committee Chair, 3CTN will request both reviewers to review their ranking and explore the possibility of reaching a consensus before the review results are finalized. |
| No  | No                | *Trial does not satisfy the peer review criteria   |

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

**5. Expedited Review of a Resubmitted Application**

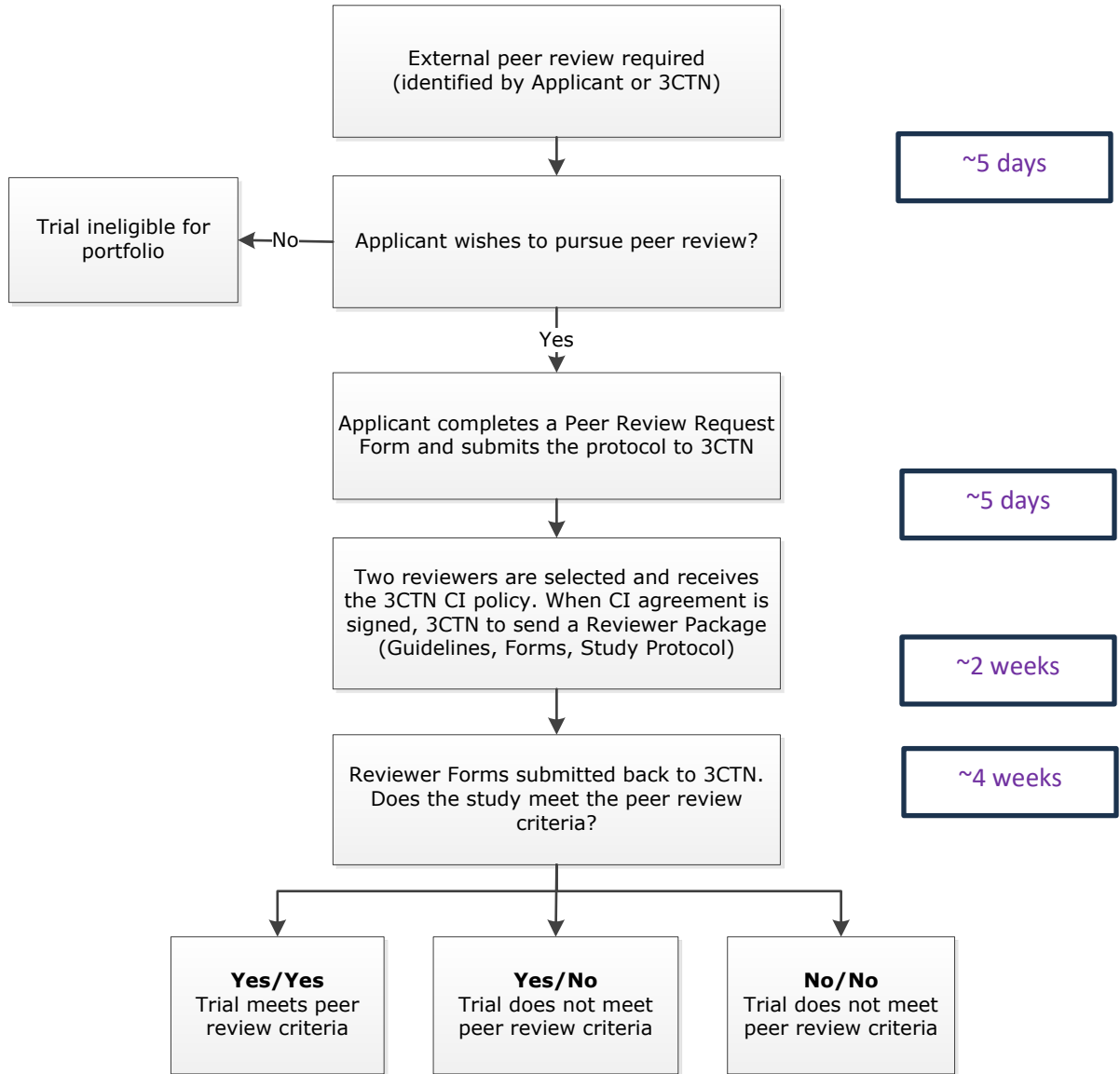
If the study PIs address the concerns raised by the reviewers with a formal written response or a revised study protocol, the response will be presented to the Portfolio Sub-Committee Chair for final review. If the Chair deems that the concerns have been properly addressed, then the study protocol can be considered approved. The Portfolio start date will be set as the re-submission date of the revised protocol.

The results of the resubmitted trial will be shared with the initial two reviewers.

**6. Communication of Results**

The final results of the PR process and the anonymized Reviewer Forms will be provided to the applicant. Any questions or concerns related to the results or comments on the Reviewer Form should be directed to the Portfolio and Informatics Manager 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)   |
| 2.1     | 02/01/2018 | Updated Section 1 language for clarification  |
| 3.0     | 07/5/2019  | <ul style="list-style-type: none"> <li>• Updated document for consistency with current Coordinating Centre internal processes</li> <li>• Added section 2.0 with process suspension timelines</li> </ul>   |
| 4.0     | 03/20/2024 | <ul style="list-style-type: none"> <li>• Added additional details under Table 1. Potential Peer Review Outcomes when both peer reviewers have not reached a consensus.</li> <li>• Added section 5.0: Expedited Review for a Resubmitted Application</li> <li>• FPR Timeline updated.</li> <li>• Some editorial changes for clarity</li> <li>• Approval by Management Committee on March 20, 2024</li> </ul> |