EORTC European Organisation for Research and Treatment of Cancer *The future of cancer therapy*	**Policy on Translational Review Committee**		
Document owner	HQ direction	Version number	1.0
Effective date	2023-02-09	Identifier	A-02-POL-01

1 Purpose

The present policy describes the independent review of translational research (TR) projects at EORTC, through the Translational Review Committee (TRC) (hereinafter referred to as projects and committee).

Projects that use samples collected in studies sponsored by EORTC are reviewed and selected to:

- align with the mission, values, and strategy of EORTC, and
- follow good research practice to answer relevant scientific questions, and
- comply with all other policies of EORTC.

2 Scope

The committee reviews

- Sample collection and translational research included in clinical study protocols.
  - Applies to all studies where EORTC is involved, irrespective of whether EORTC is leading or collaborating.
  - Includes review of translational research that is essential for study conduct and translational research with a secondary correlative objective.
- Translational research not included in clinical study protocols (secondary use of samples).
  - Applies to all projects done on behalf of EORTC, irrespective of the origin of samples.
- Requests for sharing of samples from EORTC studies, for translational research without participation of EORTC.

3 Changes since last version

Process step	**Changes since last version**
All	Initial release - Superseding POL014

4 Policy

For each project submitted to the committee for review, the chair decides whether to request the review of external reviewers, in addition to the committee members. The chair may delegate selected reviews to the scientists at EORTC Headquarters.

4.1 Criteria of evaluation

The committee uses the following criteria of evaluation:

- The scientific merit (clinical and biological relevance)
- The potential contribution of the proposed research to the interpretation of the clinical study that collected the samples
- The appropriateness of the labs and techniques suggested, including:
    - Pre-analytical issues
    - Preliminary data showing:
        - Biological basis for the use of the biomarker in the clinical study
        - Analytical validity for the collected specimens
        - Cut-offs for the intended question
        - Preliminary data that the biomarker might address the question embedded in the clinical study

4.2 Grading principles

The committee uses the following grading principles:

- Background science and hypothesis for the tumor biomarker test(s)
- Alignment of project objectives with the objectives of the clinical study:
    - For research on samples from a positive randomised controlled study, identify predictive factors for the investigational drug
    - For research on samples from other studies (for example, a negative randomised controlled study or a large non-randomized study) generate/evaluate prognostic factors and explore possible predictive factors
    - Availability of preliminary data to support the proposal
    - Appropriateness of the analytical issues:
        - Does the test work in the type of specimen available in the study?
        - Is the assay “locked down” analytically?
        - Is the cut-off locked down?
    - Statistical estimates
        - Estimate of incidence of positive vs. negative using the locked down cut-off
        - Estimate of the relative outcome/benefit according biomarker results
        - Power to detect that difference in outcomes/benefits between “positive” and “negative” in the dataset based on the number of events

4.3 Review outcome

The committee delivers one of the following outcomes for each project:

- Acceptance with or without comments
- Request for major changes and resubmission
- Rejection

EORTC Headquarters assesses operational and financial feasibility of projects accepted by the committee before granting clearance for execution.

5 Signature

This document will be electronically signed.
The signatories acknowledge that electronic signature is legally binding and equivalent to a handwritten signature.

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