

STANDARD OPERATING PROCEDURE SOP005

ETHICS COMMITTEE

TITLE: Referral of Patients to External Research

1 PURPOSE

The purpose of this SOP is to clarify the Ethics Committee procedure for consideration of proposed simple or facilitated referral of patients by a Peter MacCallum Cancer Centre (Peter Mac) clinician to an external research project.

2 SCOPE

This SOP applies to proposed simple or facilitated referrals of patients by Peter Mac clinicians to an external research project.

3 RESPONSIBILITY

It is the responsibility of referring clinicians to be aware of, and comply with, the procedure outlined in this SOP.

4 PROCEDURE

Simple or facilitated referral of a patient to an external research project falls under the general duty of care of the clinician and is not within the scope of Ethics Committee consideration. However, any activity of Peter Mac staff that constitutes a substantial contribution to an external research collaboration, such that the contribution is likely to result in a Peter Mac contributor being named on any subsequent publication, must be reviewed by the Ethics Committee.

Any clinician referring a Peter Mac patient to an external research project may refer the patient without notifying the Ethics Committee under the following conditions:

- the referral constitutes informing the patient of the availability of the external research project and provision of contact information only, OR
- the referral includes taking a blood/tissue sample and the patient has granted consent to the procedure with the knowledge that the purpose of the procedure is to screen for eligibility to participate in the external research project, AND
- the clinician takes responsibility for the 'screening' consent process as for a consent process related to any procedure performed in the best interests of the patient. AND
- the clinician takes responsibility for confirming that the external research project has received approval by a properly constituted Human Research Ethics Committee (HREC) or equivalent.

The referring clinician may seek the advice of the Ethics Committee if there are any doubts about the merits of the research, the legitimacy of the HREC approval or any consent-related aspect of the screening process or the research project.

5 RELEVANT DOCUMENTS

Professor John R Zalcberg

POLICY 21.1.1 Responsible Conduct of Research

Chief Medical Officer & Exec Director, Cancer Medicine Peter MacCallum Cancer Centre

END OF DOCUMENT

East Melbourne

Prepared by Research Ethics Coordinator

Approved by Chair, Clinical Research Governance Committee

SOP005

Version 1.0

Approved: August 2011 Review: August 2013

Page 1 of 1