

Memo

To: All Ontario Oncology Trial Centres Using OCREB
From: Ontario Cancer Research Ethics Board (OCREB)
Date: April 15, 2011
RE: Submission requirements for study-related participant materials vs. non participant materials

All study information that is **specifically intended for participants**, i.e., participant materials, including but not limited to, ICFs, ICF updates, wallet cards, advertisements, and telephone contact scripts, must be submitted to OCREB for review and approval prior to implementation. (reminder: once Provincial approval is provided, Centre-specific **administrative changes to the document** do not require further approval)

Study information/communication that is intended for **non participants**, i.e., information directed to health care professionals, including but not limited to 'Dear Dr.' letters directed to the family physician for the provision of relevant study-related information, and 'prohibited/restricted drug lists' which are directed to pharmacists for the provision of information relevant to dispensing practices for study participants, do not require REB review and approval.

References:

1. **OCREB SOP 701: 5.5 Recruitment Materials**
2. **OCREB PROVINCIAL AND CENTRE APPLICANT ROLES – Guidance 2009 AS THE PROVINCIAL APPLICANT, WHAT DO I SUBMIT TO OCREB?**
*The provincial applicant is responsible for submitting to OCREB the completed and signed provincial application form plus all of the supporting study documents including the protocol, sub-studies, budget, Investigator Brochures and/ or product monographs, provincial consent form(s), **study participant materials**, the demographic page(s) of the CRF, Health Canada NOL, etc. The checklist on the front of the provincial application form will guide you as to the required documents to be submitted.*
3. CFR: **§46.109 IRB review of research.** (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with [§46.116](#). The IRB may require that information, **in addition to that specifically mentioned** in [§46.116](#), be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

The Ontario Cancer Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: The Second Edition of the Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans (TCPS 2); The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations.



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