CANCERCARE MANITOBA CORPORATE POLICY AND PROCEDURE MANUAL		
PROCEDURE TITLE: COMPETING CLINICAL TRIALS		
SECTION: CANCERCARE	**POLICY NO: 02.015**	**APPROVED BY PRESIDENT AND CHIEF EXECUTIVE OFFICER:**
DATE: 13/05/13	**PAGE NO: 1 OF 2**	

1. PURPOSE

1.1. To ensure that the resources of CancerCare Manitoba are available and adequate before any research or innovative proposal is activated. This includes both investigators, support staff and study subjects.

1.2. To ensure a process and criteria for review of competing studies.

2. BACKGROUND

2.1. Not applicable.

3. DEFINITIONS

3.1. Competing clinical trials are treatment trials that deal with the same phase of therapy for the same disease with partial or complete overlap of eligibility criteria.

4. POLICY

4.1. Competing studies should not be open to accrual at the same time; there may, however, be exceptions. Each situation will be considered on its own merit.

4.2. The following principles should be considered in the decision regarding opening competing clinical trials:

4.2.1. The decision taken must be seen to demonstrate respect for persons;

4.2.2. All available relevant treatment options (standard care, clinical trials that are open locally, and the no treatment option) should be discussed (at least briefly) with the patient, according to the policy for informed consent ;

4.2.3. The scientific integrity of any of the studies in question should not be compromised;

4.2.4. The matter must be resolved with the Research Resource Impact Committee prior to activation of a study likely to compete with another.

5. PROCEDURES

5.1. The investigator will discuss the competing clinical trials with the appropriate Disease Site Group.

5.2. The Disease Site Group will determine whether they wish to open the competing clinical trials and if so, how they will deal with the overlap.

5.3. If the Disease Site Group decides to open competing clinical trials, they must submit their request, explanation and proposed solution to the Research Resource Impact Committee using the Competing Clinical Trials Form located on the CCMB shared drive J:/Research Resource Impact Committee and the CCMB website http://www.cancercare.mb.ca/home/cancer_research/rric/.

5.4. The Research Resource Impact Committee will review the Disease Site Groups proposed solution and will decide if this is agreeable**.** If the proposed plan is acceptable, the committee will approve.

5.5. Once approval is received from RRIC, the PI must inform other relevant individual and/or groups with rights to know in writing about the decision to open competing clinical trials**.** These include Disease Site Group members, Research Ethics Board, Clinical Investigation Office, sponsors, collaborating groups, etc.

Reference: Competing Clinical Trials in The Same Institution, by Elisa, J. Gordon and Kenneth C. Micetich, IRB Ethics & Human Research, March/April 2002 Volume 24 Number 2