



**PRMC Pre-Clinical and
Clinical Study
Concept Proposal**

Please submit Concepts to the Protocol Review and Monitoring Committee (PRMC) Chair after the concept has been approved by the appropriate Clinical Working Group.

E-mail the approved concept form to kanderson@nmcca.org.
Questions? Please call Kathy Anderson at (505) 272-7813.

INSTRUCTIONS: For Clinical Concepts, please complete all fields. For Pre-Clinical Concepts, please complete only those fields marked with an asterisk (*), using N/A to indicate fields that may not be applicable to your research project.

*Date submitted for PRMC consideration:

*Principal Investigator (PI) & Contact Information:

*Study Title:

*Study Sponsor (NMCCA, CTEP, Funds, etc.):

Lead NMCCA Clinical Site:

Other Participating Centers *and/or* NMCCA Sites (proposed):

*Phase: Pre-Clinical Pilot Phase I Phase II Phase I / II Phase III
Other (specify):

*Translational Research: Yes No

*Therapeutic Area and Disease Site(s):

*Study Agent(s):

*Source(s) of Agent(s):

*Background and Rationale:

*Hypothesis:

*(For Pre-Clinical Studies, describe Aims):

Primary Objective(s) & Endpoint(s):

Secondary and Other Objectives & Endpoints (including translational):

Specific Inclusion and Exclusion Criteria:

Required Sample Size and Feasibility of Enrollment (based on the primary endpoint):

*Expected Study Duration:

<p>*Study Assessments and Methods (For Clinical Studies: describe methods for safety and primary/secondary endpoints; For Pre-Clinical Studies: describe methods to be used):</p>	
<p>*Statistical Considerations: (1) Analysis plans and (2) Sample size justification:</p>	
<p>*References:</p>	
<p>*Scientific Review Committee (SRC) Application -</p>	<p>Please note: Proposals to utilize prospectively-collected specimens need approval from the Human Tissue Repository (HTR) via the SRC. Please call the SRC at 272-2422 for guidance before approaching the HTR. The HTR can be reached at 272-1127.</p> <p>Have you discussed the feasibility of this proposal with the HTR? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>

PI Signature: _____ *Date:* _____

Study Biostatistician Signature: _____ *Date:* _____

Clinical Working Group Leader Approval (Signature): _____ *Date:* _____