Protocol Requirements Per Organization and Trial Type						
Outline Headings and Items	**U of M Bannatyne Campus Ethics Boards**	**U of M Fort Garry Campus Ethics Boards**	**Health Canada**	**CIHR General Guidelines**	**Simplified Proposal No Intervention**	**SPIRIT (Standard Protocol Items for Interventional Trials)**
Introduction						
Protocol title			X		X	X
Protocol version			X		X	X
Protocol date					X	X
Roles (Investigators)			X		X	X
Sponsor information/contract	X					X
Abstract						
Summary of project		X		X		
Summary of Progress				X		
Background & Significance						
Problem & background (literature search)	X		X	X	X	X
Reasoning/ justification/significance			X	X	X	X
Study Aims						
Purpose (with methodology)		X				
Hypothesis	X					
Objectives	X		X	X	X	X
Study Design						
Trial design	X		X			X
Population description		X	X		X	
Trial setting - sites, countries, locations			X			X
Eligibility criteria (inclusion & exclusion criteria)	X		X		X	X
Interventions/events/tasks		X	X			X
Study procedures		X	X		X	
Outcomes/endpoint description/aims			X	X		X
Potential problems & alternative strategies				X		
Sample size with rationale	X	X	X		X	X
Study Procedures						
Timeline	X		X	X	X	X
Recruitment		X			X	X
Consent process	X	X				X
Screening			X		X	
Concomitant medications			X			
Concomitant care						X
Randomization &/or allocation sequencing			X			X
Blinding/unblinding procedure			X			X
Drug formulation, dosage regimen, washout			X			

Page 2 - Protocol Requirements Per Organization and Trial Type						
Outline Categories and Topics	**U of M Bannatyne Campus**	**U of M Fort Garry Campus**	**Health Canada**	**CIHR General Guidelines**	**Simplified No Inter-ventions**	**SPIRIT (Standard Protocol Items for Interventional Trials)**
Data collection methods & management		X				X
Data monitoring						X
Materials - questionnaires, tests, etc		X				
Biological specimen collection & storage						X
Feedback to participant		X				
Compensation		X				
Safety Monitoring Plan						
Adverse events - definition &/or monitoring	X		X			X
Minimization of potential harms	X				X	
Rescue medication & risk management			X			
Premature withdrawal/early stopping rules			X			X
Auditing/monitoring plan/interim analysis			X			X
Clinical lab parameters			X			
Protocol amendment plans						X
Analysis Plan						
Statistical analysis	X		X		X	X
Dissemination of results		X			X	X
Ethics						
Ethic approval plans						X
Alternative/previous treatments	X		X			
Potential benefits to participants	X	X				
Potential harms/risks to participants	X	X	X			
Confidentiality	X	X				X
Access to data		X				X
Deception		X				
Trial registration						X
Funding & Declarations						
Budget details/funding	X			X		X
Available resources	X					
Sponsor contract	X					
Declaration of interests						X
Literature Cited						
References			X	X	X	