MANDATORY: please ensure each item below is checked off before submitting.						
I have read, understand, and agree to the data sharing requirements. I have indicated which of the priority area(s) this application will cover (Section 4) I have indicated how this application will have public health relevance (Section 5) I have identified public health partner(s) (Section 5) I will include letters of support from the relevant public health partner(s) in the final application The budget does not exceed a total of \$1.5M						
Please submit to <u>admin1.citf@mcgill.ca</u> once complete.						
1. APPLICANT INFORMATION - ORGANIZATIONAL INFORMATION						
Language of Correspondence Preferred:	\square English	☐ French				
Legal Name of Organization:						
Legal Name of Organization in French (if applicable):						
Mailing Address:	Courier Address address):	S (if different than mailing				
Principal Applicant First Name:						
Principal Applicant Last Name:						
Mailing Address (if different from above):	Telephone No.:					
	Extension:					
Applicant E-mail Address:						
2. PROJECT INFORMATION						
Project Title:						
Duration of Project (months):	Total Amount Requ	uested:				

3. PRIORITY POPULATION				
Plea	ase select the priority population(s) as listed in the request for applications.			
	Racialized communities			
	Indigenous communities			
	Individuals of lower socioeconomic status			
	Individuals with active co-morbidities			
	Individuals with primary or secondary immune defects			
	Individuals with cancer including those receiving treatments for their malignancies			
	Individuals with autoimmunity including those receiving treatments that may alter their immune response			
	Other (please specify)			
4.	PRIORITY QUESTIONS			
Please select all that apply:				
Effe	ectiveness			
	a) What is the population effectiveness of a complete series of COVID-19 vaccine and its medium and long-term duration of protection?			
	b) What is the effectiveness of COVID-19 vaccines across specific population groups (e.g., adults of advanced age, those with high-risk medical conditions including autoimmune conditions and transplant recipients, individuals with social or occupational vulnerabilities, individuals who are pregnant or breastfeeding, children, frail adults)?			
	c) What is the effectiveness of COVID-19 vaccines in individuals who have had previous laboratory evidence of SARS-CoV-2 infection? Are there differences among those vaccinated following prior SARS-CoV-2 infection versus those who are SARS-CoV-2 naïve in terms of enhanced or altered disease upon subsequent infection by SARS-CoV-2 or by endemic coronaviruses?			
	d) What are the effectiveness (and immunogenicity) of a single dose of a COVID-19 vaccine(s) authorized as a two-dose series? How long is the duration of protection for a single dose of COVID-19 vaccine? Is there an optimal interval between the first and second dose of COVID-19 vaccine?			

- e) Is one COVID-19 vaccine superior to another? What is the effect of different dosing intervals of the vaccines? If two doses of different COVID-19 vaccine products are used, what is the effectiveness and immune response? What is the effectiveness of mixed schedules vaccines (different platforms)?
- f) Can COVID-19 vaccine be used to protect household contacts of a case from infection? Does COVID-19 vaccination decrease infectiousness and clinical illness in individuals that have already acquired infection but are asymptomatic at the time of vaccination? Is COVID-19 vaccination effective in interrupting onward transmission?

Safety

- g) What is the safety of COVID-19 vaccines across specific population groups (e.g., adults of advanced age, those with high-risk medical conditions including autoimmune conditions and transplant recipients, individuals with social or occupational vulnerabilities, individuals who are pregnant or breastfeeding, children, frail adults)?
- h) What is the safety of COVID-19 vaccines in individuals who have had previous laboratory evidence of SARS-CoV-2 infection? Are there any emerging safety signals with COVID-19 immunization that are not predicted by the current understanding of the safety profile of similar mRNA vaccines?
- i) Are some vaccines safer or more effective in certain sub-populations?
- j) Are any components of the COVID-19 vaccine more likely to induce an anaphylactic reaction?
- k) What is the incidence of rare, serious adverse events following immunization with COVID-19 vaccines?
- l) Are there any negative interactions between COVID-19 vaccination and medications for COVID or other diseases? What is the recommended timing between COVID-19 vaccines and anti-SARS-CoV-2 prophylactic or therapeutic monoclonal antibodies or convalescent plasma?

Immune response

m) What is the immunogenicity of COVID-19 vaccines across specific population groups (e.g., adults of advanced age, those with high-risk medical conditions including autoimmune conditions and transplant recipients, individuals with social or occupational vulnerabilities, individuals who are pregnant or breastfeeding, children, frail adults)?

Immune response (Cont'd)

- n) Is SARS-CoV-2 natural infection (symptomatic or asymptomatic) associated with protection against re-infection or against severe disease if reinfection occurs? How are immune responses induced by natural infection similar or different from those induced by COVID-19 vaccines?
- o) Further immunological evidence is needed in the following areas to inform effectiveness predictions:
 - i. How do immune responses change over time and how durable are immune responses against SARS-CoV-2 over the long-term?
 - ii. Which immune responses are most important for protection from infection (adaptive or innate immunity), protection from severe disease, and prevention of onward transmission?
 - iii. Are immunoglobulin (IgA/IgG/IgM) antibodies protective against SARS-CoV-2 and what is the correlate of protection?
 - iv. Is there a cell-mediated immunity correlate of protection against SARS-CoV-2?
- p) Does endemic coronavirus infection history influence the course of SARS-CoV-2 disease? Is there cross-protection or interference from antibodies/exposure to human seasonal coronaviruses when exposed to SARS-CoV-2 or vaccinated against SARS-CoV-2?
- q) What is the immunogenicity of a single dose of a COVID-19 vaccine(s) authorized as a two-dose series? How long is the duration of protection for a single dose of COVID-19 vaccine? Is there an optimal interval between the first and second dose of COVID-19 vaccine?

General Questions

r) Other pertinent issues based on preliminary data provided by the applicants.

As the situation is ever-evolving, please <u>see our website</u> for the most up-to-date information.

5. PROJECT OVERVIEW				
Provide a two page overview of the objectives, methods and public health implications of this study. Please identify public health partners clearly. Letters of support from those identified will be mandatory at the full application stage.				

Expression of Interest: SARS-CoV-2 Vaccine Safety and Effectiveness