Medical and Clinical Trial Exemptions: Guidance for Issuing and Entering Records into COVax_{ON}

December 2021

Guide for COVID-19 Vaccination Exemptions

Effective December 15, 2021, Ontarians with exemptions for medical reasons or who are participants in COVID related clinical trials will, once verified, be eligible to download an enhanced vaccine certificate (with a QR code) from the Ontario Portal. This QR code, when scanned by the Verify Ontario app and supported by ID, will allow patrons access to settings requiring proof of vaccination. Medical notes issued by out-of-province physicians will not be considered eligible for Ontario residents to receive a QR code.

Clinical Medical Exemptions

Individuals who believe they are eligible for a **medical exemption** must undergo a clinical assessment by a Ontario physician (designated as "MD") or registered nurse in the extended class (designated as "Registered Nurse (Extended Class)", "RN(EC)", "Nurse Practitioner" or "NP") to determine if they are at risk to receiving any COVID-19 vaccine.

If the risk is confirmed, a medical exemption should be recommended that includes which valid exemption is applicable along with other information as set out in the exemption template (see Appendix 2). The practitioner must confirm that the patient consents to collection, use and disclosure of their personal health information to the <u>local Public Health Unit (PHU)</u>, including any subsequent questions or communications between the practitioner and PHU as may be needed to clarify the exemption, in order to create an exemption in COVax_{ON}. See Appendix 1 for more information on obtaining consent.

The exemption template or a document that contains the same information as set out in the template, must be sent from the issuer of the exemption directly to the PHU where their practice is located for review and entering in to COVax_{ON}.

Any previously issued medical exemptions, for the purpose of obtaining a vaccine certificate for entry to settings where proof of vaccine is required, must be resent directly to the PHU. Patients may contact their MD or Nurse practitioner, to request that their exemption be reissued and sent directly to the PHU where the issuer's practice resides.

Only those individuals who are confirmed as 'designated users' who have been assigned the new permission set called "PHU Exemptions" on their $COVax_{ON}$ profile may enter medical exemption information in to $COVax_{ON}$.

Complete submissions that are sent to PHUs by December 29, 2021 should be processed by PHUs before the January 10, 2022 date in which organizations and businesses that are under

the provincial proof-of-vaccination system will be advised to no longer accept physician notes as valid medical exemptions.

Accept, Deny and Escalation of Clinical Medical Exemption Requests

If a medical exemption request is complete and meets the eligibility requirements, the designated users should create an exemption record in $COVax_{ON.}$ (see below for step by step process). If information is missing or unclear, PHUs should follow up with the issuer of the exemption and not the patient.

If the outcome of the PHU assessment is that the medical exemption request does not meet the eligibility requirements set out by the Province, the PHU can deny the request and not enter it into COVax_{ON}. The PHU should notify the issuer of the exemption request of the denial and the rationale.

If the medical practitioner feels the assessment was made in error, they can make a request to Office of the Chief Medical Officer of Health by emailing covid.immunization@ontario.ca to request a review of the exemption request.

COVID-19 Vaccine Clinical Trials

The Provincial Vaccine Contact Centre (PVCC) will provide data entry of all vaccine trial exemptions into $COVax_{ON}$. For Ontarian's participating in a Health Canada approved COVID-19 vaccine trial, the Principal Investigator or Study Director will complete the MOH Vaccine trial exemption form (see appendix for sample) and collect proof of consent for each participant that is seeking an enhanced vaccine certificate. See Appendix 1 for best practices around consent.

The Principle Investigator or Study Director must send the required form with proof of consent directly to the Provincial Vaccine Contact Centre (PVCC) for processing. The Principle Investigator or Study Director is invited to email covaxverification@ontario.ca to establish their submission procedure.

Any questions arising from the information sent to the PVCC will be addressed between the PVCC and the Principle Investigator or Study Director.

Once the form is received by the Provincial Vaccine Contact Centre, designated reviewers can take the steps described below to confirm that the documentation meets the eligibility and can be created in COVax_{ON}.

Processing time is recommended not to exceed seven business days for the Provincial Vaccine Contact Centre to input clinical trial exemptions. Complete submissions that are sent by December 29, 2021 should be processed before the January 10, 2022 date in which organizations and businesses that are under the provincial proof-of-vaccination system will be advised to no longer accept Vaccine trial forms as valid medical exemptions.

Once an exemption has been created in $COVax_{ON}$, individuals with either type of exemption may access their enhanced vaccine certificate from the $\underline{COVID-19}$ vaccination portal.

Process of Entering Different Types of Exemptions

Clinical Medical Exemptions

- 1. Review the documentation by:
 - a. ensuring that the Physician or Registered Nurse in the Extended Class (nurse practitioner) practices medicine in Ontario by checking for the name of the doctor/nurse practitioner on the College of Physicians and Surgeon's website or the College of Nurses of Ontario's website.
 - b. ensuring that the doctor or nurse practitioner is a member in good standing with the College of Physicians and Surgeons or the College of Nurses of Ontario and not currently restricted from providing medical exemptions by checking College of Physicians and Surgeon's website or the College of Nurses of Ontario's website.
 - c. ensuring that the Physician or Registered Nurse in the Extended Class has clearly identified the medical exemption and that the exemption is recognized as legitimate by Ontario by checking Ontario's exemption <u>list</u>. Ensure the submitted documentation contains all the information represented in the illustrated sample template.

Once participation in a valid medical exemption is confirmed, the designated user at the PHU enters information into $COVax_{ON}$ (see below for detailed instructions).



COVID-19 Vaccine Clinical trials

 Review the Statement of Exemption form to ensure it is complete and ensure that the clinical trial is included on the list of eligible clinical trials in Appendix C in the Ministry of Health's <u>Proof of Vaccination Guidance under the Reopening Ontario (A</u> <u>Flexible Response to COVID-19) Act, 2020</u>);

Once participation in a valid vaccine trial is confirmed, the designated user (PVCC) enters information into COVax_{ON}

Review the			Guidance for Businesses and ertifying an exemption to en	Organizations under the Reopenisure att criteria are met.
Section 1 -	individual i	nformation		
Last Name			First Name	DOB tyyyy/mm/ddi
Section 2 -	COVID-19 V	accine Clin	Ical Trial Details	
Company name				
Control number			N	V
Time period	Clinical To	riai Start Dai	p Expected yyyy/me	i End Date
Section 3 -	Business A	ddress		
Unit Numbe	stroet t	Number Str	oot Name	PO Box
City/Town		Province	Postal Code	Country
	55			Phone number

If a participant discontinues involvement in the trial, the Principle Investigator or Study Director should inform the participant that their exemption will be reviewed for revocation by the local Public Health Unit, which may impact their entry to some settings until they are fully vaccinated.

Managing suspicious documentation

An exemption request must not be entered into $COVax_{ON}$ if the exemption cannot be confirmed by the review process described above.

If appropriate, the PHU or PVCC should notify the issuer and explain the rationale for not entering the exemption into $COVax_{ON}$.

If a PHU has suspicions or concerns, a report can be filed with the College of Physicians and Surgeons of Ontario (CPSO) or to the College of Nurses of Ontario (CNO). Any concerns by the PVCC can be escalated to their manager.

Inserting Medical Exemptions into COVax_{ON}

To enter exemptions into $COVax_{ON}$ designated users must obtain the new permission set called "PHU Exemptions" on their $COVax_{ON}$ profile. Once the permission set is acquired, users will be able to enter an exemption on a client's record.

Please refer to the sections applicable to your role:

#	Section	Changes
1	USERS IMPACTED: Site Super Users, Vaccinators,	1. New Exemptions Object
	Clinic Coordinators, PCP Vaccinators, Site Staff	

Users should *NOT* be creating test/dummy data in the COVaxon Production environment. Alternatively, there is a COVaxon training environment that can be leveraged by users to practice using test/dummy data. Details for accessing this environment are located on the MOH SharePoint site that Site Leads have access to.

Section 1: Clinical Flow

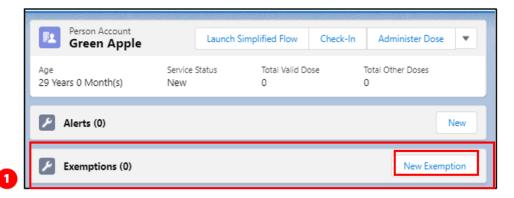
1. New Exemptions Object

Description:

Once the client record has been located and opened in COVax_{ON}, add or review any exemption on the record. Once recorded, proceed with saving the information on the client record.

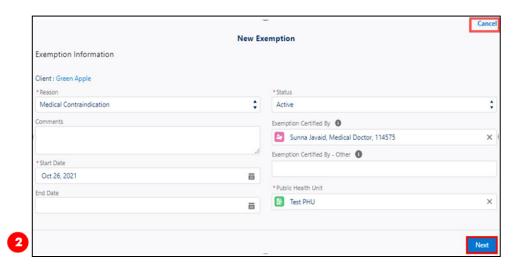
How:

1. From the client's record, under the "Exemptions" section, click "New Exemption"



- 2. Populate the following exemption fields, then click "Next" (note that a New Exemption opened in error can be discarded by clicking "Cancel"):
- Client: Defaults to client and cannot be edited
- Reason*: Select reason "Medical Contraindication" or "Vaccine Trial Participant"
- Comments: Input any comments about the exemption not captured in the designated fields
- **Start Date***: Date the exemption is effective. Defaults to the current date but can be edited. The date cannot be in the future.
- **End Date***: The date the exemption is effective to. End Date defaults to 6 months from the current date and is editable.
 - Users should update the End Date to the date indicated on the medical exemption form or vaccine trial participation form/letter.
 - If an end date has not been provided, users should use the default of 6 months from the Start Date.
 The End Date cannot be before the Start Date
 - Note that the End Date is defaulted to 6 months from the current date; if the Start Date has been edited, users should also edit the End Date accordingly
- Status*: Defaults to "Active" when creating the record, and is editable
- Exemption Certified By: The Physician or Registered Nurse in the Extended Class (Nurse Practitioner) that certified the medical exemption OR COVID-19 vaccine clinical trial Principal Investigator or Study Director (Physician or Nurse Practitioner)
- Exemption Certified By Other: Input the first name and last name of the COVID-19 vaccine clinical trial Principal Investigator or Study Director if not found in the "Exemption Certified By" look-up field. Either 'Exemption Certified By' OR 'Exemption Certified By Other' field must be completed (mandatory) in the flow to save the exemption record

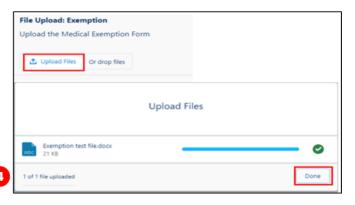
• Public Health Unit*: Defaults to PHU of the user's AO at the time the exemption is created, and is editable



3. When creating an exemption record, it is mandatory to upload the supporting documentation files. To upload the files, click "Upload Files" to select the file or select "Or drop files" to drag and drop files

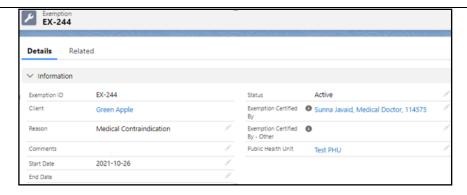


4. Once the file has uploaded, click "Done"

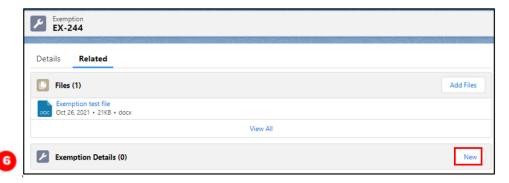


5. To continue to create the record click "Next". To return to the previous screen, click "Previous". To discard the new record from this screen, click "Cancel"

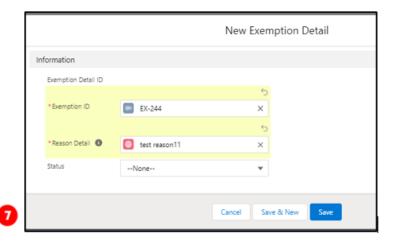




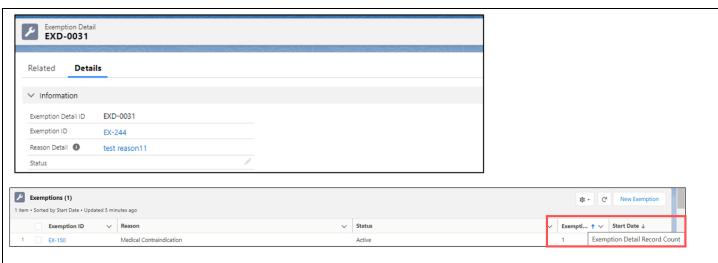
6. For medical contraindications, users must create an **Exemption Details** record to document the conditions and/or adverse events following immunization (AEFI) that qualify the client for the medical exemption. Note that steps 6 and 7 do not apply for vaccine trail participants. Go to the Exemption record's Related tab and click on "**New**" in the Exemptions Details section



7. Select the Reason Detail, then click "Save"



- Exemption Detail ID*: system generated when a new record is created
- Exemption ID*: defaults to the ID for the Exemption record. Do not edit the defaulted ID
- Reason Detail*: search and select the conditions and/or AEFI that qualifies the client for a medical exemption
- Status: defaults to blank. Can be used to mark an exemption detail as entered in error
- Once created, the record is also reflected under the Exemptions related list "Exemption Detail Record Count" column



The Exemption Detail Record count will display on the Exemptions related list

Further Context

- Exemptions can only be created, edited or viewed by users with the "PHU Exemptions" permission set.
- Users cannot delete exemption records.
- Users cannot delete any files that have been uploaded to an exemption record.
- Clients can have multiple exemption records, however if multiple active exemptions exist for the same reason, they cannot have overlapping dates.
- One exemption record can have multiple files attached.
- The exemption appears on the client record regardless of status or end date.
- An exemption that no longer applies can be set to "Inactive" status; update the "End Date" field as needed.
- The "End Date" can be in the past but cannot be before the "Start Date".
- When the "End Date" has passed, the record will automatically be set to status "Inactive".
- The "Entered in Error" status can be used if the exemption was entered by mistake.
- The "Duplicate/Merged Obsolete" status can be used when merging duplicate records that each have exemption records.
- The "Created By" field indicates the date/time/user that created the exemption record.
- The "Last Modified By" field indicates the date/time/user that last updated the exemption record.

APPENDIX 1: Consent

Best Practices for Obtaining Consent to Collect, Use, and Disclose Personal Health Information

- Where possible, the health information custodian (HIC), Principal Investigator or Study Director should obtain signed written consent from the individual to whom the information relates or their substitute decision maker.
- The HIC, Principal Investigator or Study Director may alternatively obtain consent verbally and submit a written attestation signed by the HIC, Principal Investigator or Study Director.
- The signed consent or attestation must be provided to the public health unit (PHU)/Provincial Vaccine Contact Centre (PVCC) before the information can be entered into COVaxon.
- Under the <u>Personal Health Information Protection Act</u> (PHIPA), consent must generally satisfy the following conditions:
 - 1. Must be provided by the individual to whom the information relates or their substitute decision-maker
 - 2. Must be knowledgeable
 - Individuals must understand the purpose of the collection, use or disclosure and know that they can give or withhold consent.
 - 3. Must relate to the information that will be collected, used or disclosed
 - 4. Must not be obtained through deception or coercion
- For the purposes set out in this guidance, consent should address:
 - Collection of personal health information (PHI) by the individual's physician or nurse practitioner
 - o Purpose of collection (e.g., to maintain the individual's health care record)
 - Disclosure of PHI by the physician or nurse practitioner to the PHU or PVCC and collection of PHI by the PHU or the Principal Investigator or Study Director to the PVCC
 - Purpose of collection (i.e., to create a record indicating exemption from COVID-19 immunization)
 - Note that information will be stored in a health record system under the custody and control of the Ministry of Health

- Other permitted uses and disclosures of personal health information may include:
 - Disclosure to the Chief Medical Officer of Health and Ontario public health units where the disclosure is necessary for a purpose of the Health Protection and Promotion Act.
 - Disclosure, as part of your provincial electronic health record, to health care providers who are providing care to you.
- The individual or their substitute-decision maker must be aware that they can give or withhold consent.

A sample consent text is below.

Consent (sample text)

You have provided information regarding a medical exemption from receiving a COVID-19 vaccination. By submitting this information, you consent that the information will be collected, used, and disclosed for the following purposes:

- The information will be collected by your medical practitioner for the purpose of maintaining your health care record.
- The information will be disclosed to an Ontario public health unit or provincial vaccine contact centre to create a record of personal health information indicating your exemption from COVID-19 immunization.
- The information may be exchanged between your medical practitioner and the public health unit or provincial vaccine contact centre as may be needed to clarify or verify your exemption.
- It will be used and disclosed as required for the administration of Ontario's COVID-19 vaccination program as well as other purposes authorized and required by law. For example,
 - It will be disclosed to the Chief Medical Officer of Health and Ontario public health units where the disclosure is necessary for a purpose of the *Health Protection and Promotion Act*.
 - It may be disclosed, as part of your provincial electronic health record, to health care providers who are providing care to you.

Information disclosed to the Ontario public health units will be stored in a health record system under the custody and control of the Ministry of Health.

You may also be contacted by a hospital, local public health unit, or the Ministry of Health or its agent for purposes related to your medical exemption (for example, to check on the status

(of your exemption). If you wish to receive these follow up communications by email or text,
	please indicate this using the box below.

i consent to receiving follow-up communications:	
☐ by email	
☐ by text/SMS	

If selected by email, please provide your email address:

If you consent to provide information regarding your medical exemption from receiving a COVID-19 vaccination, and then change your mind, you may withdraw consent at any time. Withdrawing your consent does not have retroactive effect but would prohibit the Ministry's subsequent uses of your personal health information unless authorized by law. If you wish to withdraw your consent or have questions about doing so you may contact the Ministry of Health at vaccine@ontario.ca.

APPENDIX 2: Sample Forms

Medical Exemption Sample Form

Sample Statement of Medical Exemption COVID-19 Immunization- Public Use

Review the exemption	to ensure all criteri	a are met.	
Section 1 -	- Individual Informat	iion	
_ast Name	,	First Name	DOB (yyyy/mm/dd
Home Add	lvoce		
Jnit Numb		Street Name	PO Box
City/Town		Province	Postal Code
Section 2 -	- Declaration of Phy	sician or Registered Nurse in th	e Extended Class (Nurse Practitio
		lame of physician or registered r	
19 immuniz COVID-19 v	zation with the currer vaccine, Moderna CO	nt COVID-19 vaccines available in VID-19 vaccine, AstraZeneca/CO	VISHIELD COVID-19 vaccine).
19 immuniz COVID-19 v	vaccine, Moderna COI Condition and/or	nt COVID-19 vaccines available in	n Ontario (<i>Pfizer-BioNTech</i> VISHIELD COVID-19 vaccine).
19 immuniz COVID-19 v	cation with the currer vaccine, Moderna CO Condition and/or sting Condition(s)	nt COVID-19 vaccines available in VID-19 vaccine, AstraZeneca/CO Adverse Event Following Immu	n Ontario (Pfizer-BioNTech VISHIELD COVID-19 vaccine). unization
19 immuniz COVID-19 v	cation with the currer vaccine, Moderna COI Condition and/or sting Condition(s) Severe allergic rea	nt COVID-19 vaccines available is WID-19 vaccine. AstraZeneca/CO Adverse Event Following Immu	n Ontain Offizer-BioNTech VISHIELD COVID-19 vaccine). unization unent of a COVID-19 vaccine
19 immuniz COVID-19 v	cation with the currer vaccine, Moderna COI Condition and/or sting Condition(s) Severe allergic rea	nt COVID-19 vaccines available is WID-19 vaccine. AstraZeneca/CO Adverse Event Following Immu	n Ontario (Pfizer-BioNTech VISHIELD COVID-19 vaccine). unization
19 immuniz COVID-19 v Selection 1. Pre-exis	zation with the currer vaccine, Moderna COI Condition and/or sting Condition(s) Severe allergic real Myocarditis prior to years old)	nt COVID-19 vaccines available is WID-19 vaccine. AstraZeneca/CO Adverse Event Following Immu	n Ontain Offizer-BioNTech VISHIELD COVID-19 vaccine). unization nent of a COVID-19 vaccine ccine series (individuals aged 12-17)
19 immuniz COVID-19 v Selection 1. Pre-exis	zation with the currer raccine, Moderna Col Condition and/or sting Condition(s) Severe allergic rea Myocarditis prior to years old) indications to Initiation	nt COVID-19 vaccines available is WID-19 vaccine. AstraZeneca/CO Adverse Event Following Immu iction or anaphylaxis to a compo- to initiating a mRNA COVID-19 va	n Ontain Offizer-BioNTech VISHIELD COVID-19 vaccine). unization nent of a COVID-19 vaccine ccine series (individuals aged 12-17)
19 immuniz COVID-19 v Selection 1. Pre-exis	ation with the currer raccine. Moderna COI Condition and/or sting Condition(s) Severe allergic real Myocarditis prior to years old) Indications to Initiation History of capillary	nt COVID-19 vaccines available in VID-19 vaccine, AstraZeneca/CO/ Adverse Event Following Immu- action or anaphylaxis to a compo to initiating a mRNA COVID-19 va ing a AstraZeneca/COVISHIELI	n Ontain Offizer-BioNTech VISHIELD COVID-19 vaccine). unization unent of a COVID-19 vaccine ccine series (individuals aged 12-17 D COVID-19 Vaccine Series
9 immuniz COVID-19 v Selection 1. Pre-exis	cation with the currer vaccine. Moderna COI Condition and/or sting Condition(s) Severe altergic real Myocarditis prior to years old) Indications to Initiation History of capillary History of cerebral	nt COVID-19 vaccines available is WID-19 vaccine. AstraZeneca/CO Adverse Event Following Immu- inction or anaphylaxis to a compo- initiating a mRNA COVID-19 va- ing a AstraZeneca/COVISHIELI v leak syndrome (CLS)	n Ontain Offizer-BioNTech VISHIELD COVID-19 vaccine). unization onent of a COVID-19 vaccine ccine series (individuals aged 12-17 D COVID-19 Vaccine Series) with thrombocytopenia

3. Adverse	Events Following COVID-19 Immuni	zation	
	Severe allergic reaction or anaphyla	axis following a COVID-19 v	vaccine
	Thrombosis with thrombocytopenia	syndrome (TTS)/Vaccine	-Induced Immune
	Thrombotic Thrombocytopenia (VITT) following the Astra Zeneca/COVISHIELD		
	COVID-19 vaccine		
	Myocarditis or Pericarditis following	a mRNA COVID-19 vaccin	е
	Serious adverse event following im	munization (e.g. results in h	nospitalization,
	persistent or significant disability/in	capacity)	
4. Other			
	Actively receiving monoclonal antib	oody therapy OR convales	cent plasma therapy for
	the treatment or prevention of COV	ID-19	
Section 3 -	Length of Exemption		
Permanent			
Time	From	То	
limited	yyyy/mm/dd	yyyy/mm/dd	
Section 4 - S	iignature		
Business Ad			PO Box
One Namber	Saccinanic		I C BOX
City/Town		Province	Postal Code
Signature of Physician or Registered Nurse in the Extended Class		Designation	Date (yyyy/mm/dd)

Clinical Trial Sample Form

Sample Statement of Exemption due to Participation in a COVID-19 Vaccine Clinical Trial Public Use

Review the Proof of Vaccination <u>Guidance for Businesses and Organizations under the Reopening</u> <u>Ontario Act</u> prior to certifying an exemption to ensure all criteria are met.					
Section 1 – Individual information					
Last Name			First Name	Ī	DOB (yyyy/mm/dd)
Section 2 - C	COVID-19 V	accine Clinical	Trial Details		
Company					
Control			N		
Time period	Clinical Tri	al Start Date	Expe	cted End Date	
	yyyy/mm.	/dd	уууу	/mm/dd	
Section 3 – Business Address					
Unit Number	Street N	umber Street N	Name	P	O Box
City/Town		Province	Postal Coo	le C	country
Email addres	SS			P	hone number

Section 4 – Declaration of Principal Investigator			
l —			
(Name of the Principal Investigator)			
certify that the above named individual is participating in a COVID-19 vaccine clinical trial that is authorized by Health Canada and specified in the Guidance for Businesses and Organizations under the <i>Reopening Ontorio Act</i> published by the Ministry of Health.			
Signature of Principal Investigator	Date (yyyy/mm/dd)		
Section 5 – Declaration of the COVID-19 Vaccine Clinical Trial Study Partic	pant		
I confirm that I am participating in the COVID-19 vaccine clinical trial detailed statement.	in this		
Signature of the COVID-19 vaccine clinical trial participant	Date (yyyy/mm/dd)		