

# **Medical and Clinical Trial Exemptions: Guidance for Issuing and Entering Records into COVaxON**

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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 [local Public Health Unit \(PHU\), 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 COVaxON. 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 COVaxON.

**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 COVaxON profile may enter medical exemption information in to COVaxON.

**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<sub>ON</sub>. (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<sub>ON</sub>. 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](mailto: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<sub>ON</sub>. 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](mailto: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<sub>ON</sub>.

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 COVaxON, individuals with either type of exemption may access their enhanced vaccine certificate from the [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 [list](#). Ensure the submitted documentation contains all the information represented in the illustrated sample template.

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

Review the [Medical Exemptions to COVID-19 Vaccination](#) guidance prior to certifying a medical exemption to ensure all criteria are met.

Section 1 - Individual Information			
Last Name	First Name	DOB (yyyy/mm/dd)	
Home Address	Street Number	Street Name	PO Box
City/Town	Province	Postal Code	

Section 2 - Declaration of Physician or Registered Nurse in the Extended Class (Nurse Practitioner)

I, \_\_\_\_\_ (Name of physician or registered nurse in the extended class) certify that, for medical reasons, the above named individual is unable to receive a COVID-19 immunization with the current COVID-19 vaccines available in Ontario (Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine, AstraZeneca/COVISHIELD COVID-19 vaccine).

Selection	Condition and/or Adverse Event Following Immunization
1. Pre-existing Condition(s)	
	Severe allergic reaction or anaphylaxis to a component of a COVID-19 vaccine
	Myocarditis prior to initiating a mRNA COVID-19 vaccine series (individuals aged 12-17 years old)
2. Contraindications to Initiating a AstraZeneca/ COVISHIELD COVID-19 Vaccine Series	
	History of capillary leak syndrome (CLS)
	History of cerebral venous sinus thrombosis (CVST) with thrombocytopenia
	History of heparin-induced thrombocytopenia (HIT)
	History of major venous and/or arterial thrombosis with thrombocytopenia following any vaccine

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

## COVID-19 Vaccine Clinical trials

1. 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 [Proof of Vaccination Guidance under the Reopening Ontario \(A Flexible Response to COVID-19\) Act, 2020](#);

Once participation in a valid vaccine trial is confirmed, the designated user (PVCC) enters information into COVaxON

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 COVaxON 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 COVaxON.

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 COVaxON

To enter exemptions into COVaxON designated users must obtain the new permission set called "PHU Exemptions" on their COVaxON 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, Clinic Coordinators, PCP Vaccinators, Site Staff	1. New Exemptions Object

**Important Note for all COVaxON Users:**

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

Review the Proof of Vaccination Guidance for Businesses and Organizations under the Reopening Ontario Act prior to certifying an exemption to ensure all criteria are met.

Section 1 – Individual Information

Last Name First Name DOB yyyy/mm/dd

Section 2 – COVID-19 Vaccine Clinical Trial Details

Company name

Control number

Time period Clinical Trial Start Date Expected End Date  
yyyy/mm/dd yyyy/mm/dd

Section 3 – Business Address

Unit Number Street Number Street Name PO Box

City/Town Province Postal Code Country

Email address Phone number

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 COVaxON, 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"**

The screenshot shows the COVaxON interface for a client named Green Apple. The client's account information is displayed at the top, including Age (29 Years 0 Month(s)), Service Status (New), Total Valid Dose (0), and Total Other Doses (0). Below this, there are sections for Alerts (0) and Exemptions (0). The Exemptions (0) section is highlighted with a red box, and a 'New Exemption' button is visible within it. A red circle with the number '1' is placed next to the 'Exemptions (0)' section.

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

**New Exemption** Cancel

Exemption Information

Client : Green Apple

\* Reason: Medical Contraindication

\* Status: Active

Comments

\* Start Date: Oct 26, 2021

End Date

Exemption Certified By: Sunna Javaid, Medical Doctor, 114575

Exemption Certified By - Other

\* Public Health Unit: Test PHU

Next

- 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

**File Upload: Medical Contraindication** Cancel

Upload the Medical Exemption or Vaccine Trial Participant form

Upload Files Or drop files

Previous Next

- Once the file has uploaded, click "**Done**"

**File Upload: Exemption**

Upload the Medical Exemption Form

Upload Files Or drop files

**Upload Files**

Exemption test file.docx  
21 KB

1 of 1 file uploaded

Done

- 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**"

**File Upload: Medical Contraindication** Cancel

Upload the Medical Exemption or Vaccine Trial Participant form

Upload Files Or drop files

Previous Next

Exemption  
EX-244

Details Related

Information

Exemption ID	EX-244	Status	Active
Client	Green Apple	Exemption Certified By	Sunna Javaid, Medical Doctor, 114575
Reason	Medical Contraindication	Exemption Certified By - Other	
Comments		Public Health Unit	Test PHU
Start Date	2021-10-26		
End Date			

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

Exemption  
EX-244

Details Related

Files (1) Add Files

Exemption test file  
Oct 26, 2021 • 21KB • docx

View All

Exemption Details (0) New

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

New Exemption Detail

Information

Exemption Detail ID

\*Exemption ID EX-244

\*Reason Detail test reason11

Status --None--

Cancel Save & New 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



Exemption Detail  
**EXD-0031**

Related
Details

Information

Exemption Detail ID
EXD-0031

Exemption ID
EX-244

Reason Detail ⓘ
test reason11

Status

Exemptions (1)

1 item • Sorted by Start Date • Updated 5 minutes ago

☐
Exemption ID

☐
Reason

☐
Status

☒
Exempti...

☐
Start Date

1
☐
EX-150
Medical Contraindication
Active

1
Exemption Detail Record Count

- 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 [Personal Health Information Protection Act](#) (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
    - 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](mailto:vaccine@ontario.ca).

## APPENDIX 2: Sample Forms

### Medical Exemption Sample Form

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

Review the [Medical Exemptions to COVID-19 Vaccination](#) guidance prior to certifying a medical exemption to ensure all criteria are met.

##### Section 1 – Individual Information

Last Name		First Name		DOB (yyyy/mm/dd)
<b>Home Address</b>				
Unit Number	Street Number	Street Name		PO Box
City/Town		Province	Postal Code	

##### Section 2 – Declaration of Physician or Registered Nurse in the Extended Class (Nurse Practitioner)

I, \_\_\_\_\_ (Name of physician or registered nurse in the extended class) certify that, for medical reasons, the above named individual is unable to receive a COVID-19 immunization with the current COVID-19 vaccines available in Ontario (Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine, AstraZeneca/COVISHIELD COVID-19 vaccine).

Selection	Condition and/or Adverse Event Following Immunization
<b>1. Pre-existing Condition(s)</b>	
	Severe allergic reaction or anaphylaxis to a component of a COVID-19 vaccine
	Myocarditis prior to initiating a mRNA COVID-19 vaccine series (individuals aged 12-17 years old)
<b>2. Contraindications to Initiating a AstraZeneca/ COVISHIELD COVID-19 Vaccine Series</b>	
	History of capillary leak syndrome (CLS)
	History of cerebral venous sinus thrombosis (CVST) with thrombocytopenia
	History of heparin-induced thrombocytopenia (HIT)
	History of major venous and/or arterial thrombosis with thrombocytopenia following any vaccine

##### 3. Adverse Events Following COVID-19 Immunization

	Severe allergic reaction or anaphylaxis following a COVID-19 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 vaccine
	Serious adverse event following immunization (e.g. results in hospitalization, persistent or significant disability/incapacity)

##### 4. Other

	Actively receiving monoclonal antibody therapy OR convalescent plasma therapy for the treatment or prevention of COVID-19
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##### Section 3 – Length of Exemption

Permanent		
Time limited	From yyyy/mm/dd	To yyyy/mm/dd

##### Section 4 – Signature

<b>Business Address</b>			
Unit Number	Street Number	Street Name	PO 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 Guidance for Businesses and Organizations under the Reopening Ontario Act](#) prior to certifying an exemption to ensure all criteria are met.

##### Section 1 – Individual Information

Last Name	First Name	DOB (yyyy/mm/dd)
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##### Section 2 – COVID-19 Vaccine Clinical Trial Details

Company name		
Control number		
Time period	Clinical Trial Start Date yyyy/mm/dd	Expected End Date yyyy/mm/dd

##### Section 3 – Business Address

Unit Number	Street Number	Street Name	PO Box
City/Town		Province	Postal Code
Email address		Phone number	

##### Section 4 – Declaration of Principal Investigator

I, \_\_\_\_\_ (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 Reopening Ontario Act 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 Participant

I confirm that I am participating in the COVID-19 vaccine clinical trial detailed in this statement.

Signature of the COVID-19 vaccine clinical trial participant \_\_\_\_\_ Date (yyyy/mm/dd) \_\_\_\_\_