

### REQUEST FOR EXEMPTION FROM COVID-19 VACCINE FOR MEDICAL REASONS

**Instructions:** This form should be completed by a Healthcare Worker requesting a medical exemption from Essentia Health's COVID-19 vaccination requirement. Parts of this form should be completed by the Healthcare Worker's medical provider.

To be completed by the H	ealthcare Worker	calcilled to their 3 illedical prov	ider.		
Please <i>print</i> the following in					
Name:	iornation.	Date of Birth:			
E-mail*:		Phone No.:			
Status (employee/		Department			
vendor/contractor/		served/			
student/clergy, etc.):		vendor name:			
Job Title/Role:		-			
*You will receive the decision	on on your exemption request via email, please	ensure you regularly check you	ır email.		
Please check the box (or boxes) that best describe the services you perform for Essentia:    regularly (at least three times a month) come within six feet of other Essentia Health Healthcare Workers.    regularly (at least three times a month) come within six feet of Essentia Health patients.    regularly (at least three times a month) come within six feet of patients who are immunocompromised.    rarely (less than three times a month) come within six feet of patients or other Healthcare Workers (e.g., I am a remote worker).    Please describe the services you perform for Essentia Health. Include information about the amount and type of contact you have with patients and other healthcare workers. Include information about the types of patients you work with, if any (e.g., cancer, NICU, elective surgery, family practice patients):					
Healthcare Worker Certification and Declination of Vaccination  By my signature below, I certify that I have a medical condition which will be adversely affected by receiving the COVID-19 vaccination and I request a medical exemption from COVID-19 vaccination. By my signature below, I understand that any intentional misrepresentation contained in this request may result in disciplinary action. I also acknowledge that my request for an exception may not be granted if it is unreasonable or it creates an undue hardship on Essentia.  I understand that due to my status as a healthcare worker, I may be at risk of acquiring infection while performing services for Essentia Health. In addition, I may spread COVID-19 to patients, other healthcare workers, and my family, even if I have no symptoms. This can result in serious infection, particularly in persons at high risk for COVID-19 complications.  I have received education about the effectiveness of the COVID-19 vaccination as well as the adverse events. However, I decline the COVID-19 vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring COVID-19, potentially resulting in transmission to patients. If in the future I want to be vaccinated with a COVID-19 vaccine, I can provide documentation to Essentia Health and will no longer be required to mask in certain situations.  I attest that I will wear a mask as required anytime I am within Essentia Health facilities if I do not receive the COVID-19 vaccination. I will not receive a COVID-19 Vaccine Clip if I am not Fully Vaccinated.  Healthcare Worker Signature:  Date:					
PLEASE MAIL OR EMAIL PAGES 1 TO 3 OF THE COMPLETED FORM TO: Essentia Health COVID Vaccine Team OR Email: FluCOVIDVaccination@essentiahealth.org 407 East Third St., BSC — Human Resources Duluth, MN 55805					
**For Essentia Health use o	nnlv**				

Date:

Denied (Initial)

Approved (Initial)

To be completed by the Healthcare worker's medical provider: Dear Medical Provider,			
Essentia Health requires COVID-19 vaccination for all Healthcare Workers. Essentia Health and Healthcare Workers have a shared responsibility to take reasonable measures to avoid causing harm to patients and to prevent occupationally and community-acquired COVID-19 infections.			
The above-named Healthcare Worker is requesting an exemption from this vaccination requirement. A medical exemption from COVID-19 vaccination may be allowed for certain contraindications recognized by the CDC, and other medical conditions that prevent the Healthcare Worker from being vaccinated safely. For informational purposes and ease of reference, we included an informational sheet with vaccine components and contraindications in this packet.			
My patient,, should not be immunized against COVID-19 for the following reasons, please check all that apply:			
<ul> <li>Severe or immediate allergic reaction to vaccine ingredient. Individual has a history of a severe allergic reaction (e.g., anaphylaxis) to an ingredient of a COVID vaccine or an immediate allergic reaction to an ingredient of the vaccine.</li> <li>"Allergic reaction" does not include sore arm, local reaction, or subsequent upper respiratory tract infection</li> <li>The Pfizer and Moderna vaccines contain polyethylene glycol. None of the COVID vaccines contain eggs, gelatin, latex, or preservatives, metals (such as iron, nickel, cobalt, lithium, rare earth alloys) or any manufactured products (such as microelectronics, electrodes, carbon nanotubes, or nanowire semiconductors)).</li> </ul>			
Vaccine ingredient(s) the patient is allergic to:			
Can the patient receive a different COVID-19 vaccine product that does not contain this ingredient? If not, why not?			
Please check all allergic reactions that apply:  Anaphylaxis attributable to the ingredient  Hives within 24 hours of exposure to an ingredient of the vaccine  Swelling of the lips, throat, or tongue within a few hours of exposure to a vaccine ingredient  Difficulty breathing within a few hours of exposure to the vaccine ingredient  Other (Complete page 3 and attach supporting records and a narrative of the allergic reaction.)			
Severe or immediate allergic reaction to previous dose of the COVID-19 Vaccine. Individual had a severe or immediate allergic reaction to a previous dose of the COVID-19 vaccine ("Allergic reaction" does not include sore arm, local reaction, or subsequent upper respiratory tract infection).			
COVID-19 Vaccine (Pfizer, Moderna, J&J/Janssen) the patient is allergic to:			
Can the patient receive a different COVID-19 vaccine product? If not, why not?			
Please check all allergic reactions that apply:  Anaphylaxis attributable to the COVID-19 vaccine Hives within 24 hours of receiving the COVID-19 vaccine Swelling of the lips, throat, or tongue within a few hours of the COVID-19 vaccine Difficulty breathing within a few hours of the COVID-19 vaccine Other (Complete page 3 and attach supporting records and a narrative of the allergic reaction.)			
My patient needs a deferral of the COVID-19 vaccine requirement. They can get the COVID-19 vaccine after			
(date). Please check reason for deferral request:			
□ COVID-19 treatment with monoclonal antibodies/convalescent plasma. Last treatment day was: History of multisystem inflammatory syndrome. Date of diagnosis: Last day of illness: Other (Complete page 3 and attach supporting records and a narrative reason for deferral.)			
□ <b>Other</b> – <u>Please complete page 3</u> of this form			



## Request for Medical Exemption from COVID-19 Vaccination Form

To be completed by Provider if "Other" was selected on page 2; or by the Healthcare Worker if their provider was

Please provide detailed information as requested to ensure an individualized and timely review of the request (these requests will be reviewed on a case-by-case basis).

Please see the enclosed information for more information about contraindications and the ingredients of the vaccine products. Please note that the following are generally not considered contraindications to the COVID vaccines:

- Allergy to oral medications (including the oral equivalent of an injectable medication)
- History of food, pet, insect, venom, environmental, latex, etc., allergies
- Family history of allergies

Provider Name:

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1)	Please describe the Healthcare Worker's medical condition and why their medical condition requires them to be exempted from the requirement to receive the COVID-19 vaccine.
2)	If the Healthcare Worker has had an adverse reaction to the COVID-19 vaccine or vaccine components, please describe the circumstances of their adverse health reaction to the COVID-19 vaccine or vaccine components. Indicate if they were treated by a provider, symptoms, severity of symptoms, and timing /duration of symptoms after vaccination. You may attach a separate narrative if needed.
3)	Does their medical documentation support their adverse health reaction to the COVID-19 vaccine? If yes, please attach medical documentation to your exemption request.  ☐ Yes ☐ No
To be o	completed by Provider:
By my	y box that has been checked PLEASE ATTACH SUPPORTING DOCUMENTATION or MEDICAL RECORDS <sup>1</sup> signature below, I certify that my patient has the above contraindication and I support their request for a medical ion from the required COVID-19 vaccination.
Provide	er Signature: Date:

Provider Phone No:\_\_\_\_

<sup>1</sup> The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits employers and other entities covered by GINA Title II from requesting or requiring genetic information of an individual or family member of the individual, except as specifically allowed by this law. To comply with this law, we are asking that you not provide any genetic information when responding to this request for medical information. "Genetic information" as defined by GINA, includes an individual's family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual's family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services.

## Helpful Information about the COVID-19 Vaccines for Providers

(Accurate as of 8/4/2021)

### Ingredients included in COVID-19 vaccines

The following is a list of ingredients for the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines reported in the prescribing information for each vaccine\*

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication- incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
ingredients	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

<sup>\*</sup> None of the vaccines contain eggs, gelatin, latex, or preservatives. All COVID-19 vaccines are free from metals such as iron, nickel, cobalt, lithium, rare earth alloys or any manufactured products such as microelectronics, electrodes, carbon nanotubes, or nanowire semiconductors. Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients for vaccines and medications can be found in the package insert. The CDC's vaccine excipient summary and the National Institutes of Health DailyMed can also be used as a resource.

Source: CDC - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C

### Triage of people presenting for COVID-19 vaccination

CONTRAINDICATION TO VACCINATION		MAY PROCEED WITH VACCINATION
History of the following:	Among people without a contraindication, a history of:	Among people without a contraindication or precaution, a history of:
<ul> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine†</li> <li>Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†</li> </ul>	<ul> <li>Any immediate allergic reaction* to other vaccines or injectable therapies‡</li> <li>Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#</li> </ul>	<ul> <li>Allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>Family history of allergies</li> </ul>
Actions:	Actions:	Actions:
<ul> <li>Do not vaccinate.</li> <li>Consider referral to allergist-immunologist.</li> <li>Consider other vaccine alternative.†</li> </ul>	<ul> <li>Risk assessment**</li> <li>Consider referral to allergist-immunologist</li> <li>30-minute observation period if vaccinated</li> </ul>	<ul> <li>30-minute observation period: people with history of anaphylaxis (due to any cause)</li> <li>15-minute observation period: all other people</li> </ul>

<sup>†</sup> See above for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

<sup>\*</sup> Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

‡People with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction

#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

\*\*The following considerations can be used to help the vaccination provider conduct a risk assessment for vaccination in individuals with a precaution to vaccination:

- Risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation)
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)
- The unknown risk of anaphylaxis (including fatal anaphylaxis) following COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where <u>appropriate medical care</u> is immediately available for anaphylaxis. Note, for people with a contraindication to another type of COVID-19 vaccines (e.g., mRNA vaccines), vaccination with another type (e.g., Janssen viral vector vaccine) should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

Source: CDC - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C

### Prior COVID-19 Illness; Deferrals

You should get a COVID-19 vaccine regardless of whether you already had COVID-19. That's because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19. Learn more about why getting vaccinated is a safer way to build protection than getting infected here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html.

If you were treated for COVID-19 with monoclonal antibodies or convalescent plasma, you should wait 90 days before getting a COVID-19 vaccine. Talk to your healthcare professional if you are unsure what treatments you received or if you have more questions about getting a COVID-19 vaccine.

If you or your child have a history of multisystem inflammatory syndrome in adults or children (MIS-A or MIS-C), consider delaying vaccination until you have recovered from being sick and for 90 days after the date of diagnosis of MIS-A or MIS-C. Learn more about the clinical considerations people with a history of MIS-A or MIS-C here:

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination.

Source: CDC - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/prepare-for-vaccination.html

# <u>American College of Obstetricians and Gynecologists – COVID-19 Vaccination Considerations for Obstetric-Gynecologic Care</u>

"ACOG recommends that all eligible persons, including pregnant and lactating individuals, receive a COVID-19 vaccine or vaccine series. Obstetrician-gynecologists and other women's health care practitioners should lead by example by being vaccinated and encouraging eligible patients to be vaccinated as well."

Source: ACOG - https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care

## **Emergency Use Authorization Fact Sheets for Healthcare Providers**

- PFIZER-BIONTECH COVID-19 VACCINE: https://www.fda.gov/media/144413/download
- MODERNA COVID-19 VACCINE: <a href="https://www.fda.gov/media/144637/download">https://www.fda.gov/media/144637/download</a>
- JANSSEN (J&J) COVID-19 VACCINE: https://www.fda.gov/media/146304/download

### COVID-19 Advisory Committee on Immunization Practices ("ACIP") Vaccine Recommendations

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

### U.S. Food & Drug Administration ("FDA") COVID-19 Vaccine News and Updates

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

#### Resources for Addressing Myths about the COVID-19 Vaccines

- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html
- https://newsnetwork.mayoclinic.org/discussion/covid-19-vaccine-myths-debunked/