Johnson & Johnson/Janssen COVID-19 Vaccine

Beth Israel Lahey Health Acknowledgement of Receipt of COVID-19 Vaccine for Staff

The purpose of COVID-19 vaccination is to reduce the risk of infection by the virus that causes Coronavirus Disease 2019 (COVID-19) and lessen the risk of becoming seriously ill should infection occur.

As a member of the BILH workforce, please understand that:

- Your participation in this vaccine program is voluntary but strongly encouraged
- If you choose not to take part, your decision will in no way affect your employment or BILH work status
- If at any time you decide you are not ready to receive a COVID-19 vaccine, we encourage you to discuss your options with your health care provider and schedule when ready

There are currently three COVID-19 vaccines: two mRNA vaccines (Pfizer-BioNTech and Moderna) and one viral vector vaccine **(Johnson & Johnson (J&J)/Janssen)** (collectively the "EUA Vaccines") authorized by the Food and Drug Administration ("FDA") under Emergency Use Authorization ("EUA"). The FDA may issue an EUA based on a declaration by the Secretary of the Department of Health and Human Services that circumstances justify the emergency use of drugs and biological products during the COVID-19 pandemic if certain criteria are met. The criteria for the COVID-19 J&J/Janssen vaccine you are being offered today is explained in more detail in the EUA Fact Sheets linked below.

Please review the EUA Fact Sheet for Recipients and Caregivers online for complete details on the vaccine and possible side effects: **www.janssencovid19vaccine.com**

You should not receive the J&J/Janssen COVID-19 vaccine if you have a history of severe allergy (anaphylaxis) or immediate reaction of any kind (e.g., anaphylaxis, difficulty breathing, hives, swelling around the mouth, throat or eyes) to any component of the vaccine (such as polysorbate).

Reasons to Delay Vaccination:

- If you have a fever (temperature of 100.4 degrees or higher), chills or any symptoms of COVID-19 infection, contact your primary health care provider for COVID-19 testing prior to vaccination.
- If you were recently diagnosed with COVID-19 or are on quarantine due to an exposure, you should wait until your primary health care provider recommends ending isolation or quarantine prior to vaccination.
- In the very rare instance you have been diagnosed with Multisystem Inflammatory Syndrome (MIS) following COVID-19 infection, we recommend that you wait 90 days after diagnosis to be vaccinated.
- If you have received (or may have received in a clinical trial) a monoclonal antibody or convalescent plasma for COVID-19 treatment or prevention: you should wait 90 days after the treatment date before getting vaccinated so that the vaccine will be as effective as possible.

Other Considerations Prior to Vaccination:

- If you are pregnant, lactating (breastfeeding) or planning to become pregnant, we recommend that you have a conversation with your primary health care provider about whether vaccination is right for you.
- **If you have a history of immediate allergic reaction (such as anaphylaxis, difficulty breathing, hives, or swelling around the mouth, throat or eyes) to any other vaccine or injectable (intramuscular, intravenous or subcutaneous) medication in the past, you must inform us so that the appropriate longer post-vaccination monitoring (30 minutes) may be performed.**

Precaution for Women Aged 18-49:

Due to a rare risk of blood clots related to a condition called thrombosis with thrombocytopenia (TTS) associated with the use of the J&J/Janssen vaccine, BILH recommends that while alternate options are available, women aged 18-49 should be offered a mRNA vaccine (Pfizer-BioNTech or Moderna) as a first choice at our vaccination sites. If a single-dose vaccine is preferred or receipt of an mRNA vaccine is not feasible (due to a history of allergy), you may proceed with vaccination with the J&J/Janssen vaccine but should be informed of the rare risk of blood clots.

Precaution for Patients with a History of Heparin-Induced Thrombocytopenia:

Until more information becomes available, we currently recommend that patients with a history of heparin-induced thrombocytopenia (HIT) receive a mRNA vaccine. If a single-dose vaccine is preferred or receipt of an mRNA vaccine is not feasible (due to a history of allergy), we recommend evaluation by a hematologist prior to use of the J&J/Janssen vaccine.

Information About the Rare Risk of Blood Clots:

Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the J&J/Janssen vaccine. Most people who developed these blood clots and low levels of platelets were females ages 18-49 years, with symptoms beginning approximately one to two weeks following vaccination.

You should seek medical attention right away if you have any of the following symptoms after receiving J&J/Janssen COVID-19 vaccine: shortness of breath, chest pain, leg swelling, persistent abdominal pain, severe or persistent headaches or blurred vision, easy bruising or tiny blood spots under the skin other than at the site of the injection.

Information About the Rare Risk of Guillain-Barré Syndrome (GBS):

A small number of cases of vaccine-associated GBS (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) have been seen after receipt the J&J/Janssen vaccine. If you have had a history of GBS related to a vaccine or other causes, we recommend a discussion with your primary physician prior to receipt of the J&J/Janssen vaccine.

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Required Post-Vaccination Observation Period:

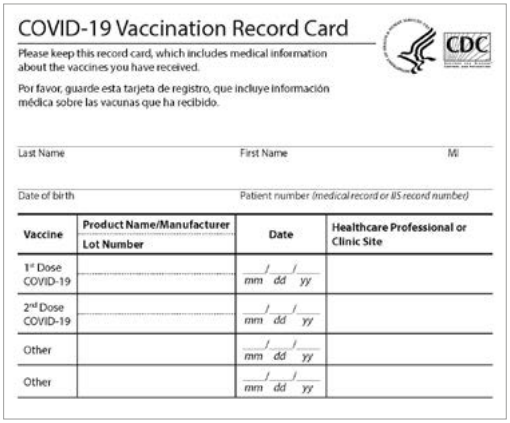
You will be monitored for any signs of an allergic reaction immediately after the vaccination (minimum 15 minutes, 30 minutes if prior severe allergic reaction). Some symptoms of allergic reaction are rash, wheezing, difficulty breathing, dizziness and fainting, swelling around the mouth, throat, or eyes. This is not an exhaustive list. Please notify us immediately if you notice any of these symptoms or have any other concerns.

What to Expect After Your COVID-19 Vaccination:

It is very important that you contact Employee Health about any side effects that you experience after vaccination. If any serious health problem occurs, particularly within 6 weeks of vaccination and certainly one that requires you to go to the emergency department or hospital – notify Employee Health as soon as possible. Please notify Employee Health even if you are uncertain if the problem is related to the vaccine in any way.

In addition, please report all vaccine side effects to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) online, **vaers.hhs.gov/reportevent.html**, or via the VAERS toll-free number at 1-800-822-7967. Employee Health is available to assist with this reporting if needed.

Even after you get your vaccine, you will need to keep wearing a mask that covers your nose and mouth in certain situations as outlined in the Massachusetts Mask Order (**www.mass.gov/info-details/mask-up-massachusetts**) and to clean your hands often. This gives you and others the best protection from catching the virus.



COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Last Name | First Name | MI

Date of birth | Patient number (medical record or IIS record number)

Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1st Dose COVID-19		mm dd yy	
2nd Dose COVID-19		mm dd yy	
Other		mm dd yy	
Other		mm dd yy	

Only one dose of the J&J/Janssen vaccine is recommended. You do not need to book additional appointments after your vaccination is completed. We are following the current FDA and CDC guidance for vaccination and are not recommending booster doses at this time due to limited data on safety and efficacy.

Reminder - The vaccine you receive will be listed on a vaccination card provided to you. Please keep this card for your COVID-19 Vaccination Record.

Consider enrolling in the CDC v-safe Tool (**vsafe.cdc.gov**) – a smartphone after vaccination health checker for people who receive COVID-19 vaccines.

If you have any questions about side effects, please consult with your primary health care provider.

Full Name (Please Print): _____ **Date of Birth:** _____

Department: _____ **Job Title:** _____

Work E-Mail: _____ **Supervisor:** _____

BILH Home Institution (please circle):

Addison Gilbert
BID-Milton
BILH Continuing Care
BILH Cambridge
LHMC
Anna Jaques
BID-Needham
BILH Primary Care
BILH Perf. Network
LOC-Danvers
Bayridge
BILH Behavioral Services
Beverly Hospital
HMFP
Mt. Auburn
BID-Plymouth
Lahey Health
Shared Services
NEBH
BIDMC
Winchester
Other: _____

TO BE ENTERED BY BILH VACCINATOR

Date Given: _____

Manufacturer: _____

Given By: _____

Lot #: _____

Expiration Date: _____

EUA Fact Sheet Given: _____

2nd Dose Required: Y N _____

Date of 2nd Dose: _____

Deltoid Site: L R _____

Allergies: _____

(30-minute observation period required if history of severe allergy to any vaccine or injectable medication)

Statement of Acknowledgement of Receipt of COVID-19 Vaccine

My signature below indicates that I have read the information about COVID-19 vaccine, received a copy of the Emergency Use Authorization Fact Sheet for Recipients and Caregivers, read the fact sheet and addressed any necessary personal medical concerns with my personal care provider.

Signature: _____ **Date:** _____