**Non Patient-Specific Standing Order for the Administration of the**

**Gray Cap Pfizer-BioNTech COVID-19 Vaccine**

**(Updated 05/23/2022)**

**Purpose:** To reduce morbidity and mortality from COVID-19 by administering the “**gray cap**” Pfizer-BioNTech COVID-19 vaccination as permitted by the policy and order sections of this Order.

**Policy:** Under this non patient-specific standing order, [insert clinical staff titles] who are [employees, volunteers, [and/or] contractors] of the [Insert Organization Name] may administer the Pfizer-BioNTech COVID-19 vaccination to eligible individuals, as permitted by its Emergency Use Authorization (EUA), as applicable, state and federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness (PREP) Act declarations, ACIP recommendations, and the CDC’s and New York State’s Vaccination Program.

**Procedure:**

1. This standing order is for use of Pfizer-BioNTech COVID-19 vaccine vials with **gray caps** and labeled for use persons age 12 years and older.
   1. If using Pfizer-BioNTech COVID-19 vaccine vials with purple caps and labeled “Dilute Before Use”, consult the standing order for administration of Pfizer-BioNTech COVID-19 purple cap vaccine vials.
   2. If vaccinating persons between the ages of 5 through 11 years, consult the standing orders for administration of Pfizer-BioNTech COVID-19 vaccine to children age 5 through 11 years.
2. Assess persons 12 years of age or older for COVID-19 vaccine history and schedule based on the following criteria:
   1. **Moderate to severe immunocompromise**: Administer a three (3) dose primary series of Pfizer-BioNTech COVID-19 vaccine followed by two booster doses after completing the primary series. A patient’s clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination, however there is no requirement for proof of immunocompromise nor prescription from a patient’s clinical team. This is to prevent additional barriers to vaccination for this vulnerable population.
      1. Primary series
         1. No COVID-19 vaccine, or one or more doses of COVID-19 vaccine product(s) that holds neither an emergency use listing (EUL) by the World Health Organization (WHO) nor an EUA by the US Food and Drug Administration (FDA): Administer the first dose of Pfizer-BioNTech COVID-19 vaccine according to the procedure described herein.
         2. One (1) previous dose of Pfizer-BioNTech COVID-19 vaccine administered 21 or more days prior to the date of vaccine administration: Administer the second dose of Pfizer-BioNTech COVID-19 vaccine.
         3. One (1) previous dose of a COVID-19 vaccine product that holds an EUL by the WHO but does not hold an EUA by the FDA, administered 28 or more days prior to the date of vaccine administration: administer one dose of the Pfizer-BioNTech COVID-19 vaccine.
         4. One (1) previous dose of Janssen (Johnson & Johnson) COVID-19 vaccine administered 28 or more days prior to the date of vaccine administration: Administer an additional (second) dose of Pfizer-BioNTech COVID-19 vaccine.
         5. Two (2) doses of Pfizer-BioNTech COVID-19 vaccine, of COVID-19 vaccine product(s) that holds an EUL by the WHO or of a heterologous (mixed) series of a COVID-19 vaccine product that holds an EUL by the WHO and a dose of Pfizer-BioNTech COVID-19 vaccine, with the second dose administered 28 or more days prior to the date of vaccine administration: Administer an additional (third) dose of Pfizer-BioNTech COVID-19 vaccine.
      2. First booster dose:
         1. A complete three (3) dose primary series of Pfizer-BioNTech COVID-19 vaccine, a COVID-19 vaccine that holds an EUL by the WHO or of a heterologous series of COVID-19 vaccines that hold an EUL by the WHO and Pfizer-BioNTech COVID-19 vaccine, with the third dose administered at least three (3) months prior to the date of vaccine administration: Administer a first booster dose of Pfizer-BioNTech COVID-19 vaccine.
         2. An initial dose of Janssen (Johnson & Johnson) COVID-19 vaccine followed by an additional dose of Pfizer-BioNTech COVID-19 vaccine, with the additional dose administered at least two (2) months prior to the date of vaccine administration: Administer a first booster dose of Pfizer-BioNTech COVID-19 vaccine.
      3. Second booster dose:
         1. A complete primary series of COVID-19 vaccines as described in this section and one (1) booster dose of any authorized or approved COVID-19 vaccine at least four (4) months before the date of vaccine administration: Administer a second booster dose of Pfizer-BioNTech COVID-19 vaccine.
      4. Revaccination: Recipients of hematopoietic stem cell transplant, CAR-T-cell, or other B-cell depleting therapies who received doses of COVID-19 vaccine prior to or during treatment should be revaccinated for all doses received before or during treatment, with the first revaccinated dose given at least 12 weeks after completing treatment. Based on the clinical judgement of the patient’s clinical team, revaccination may also be considered once immune competence is regained for people who received COVID-19 vaccine doses during chemotherapy or radiation treatment.
   2. **All other individuals age 12 years and older:**
      1. No COVID-19 vaccine, or either a complete or incomplete series of COVID-19 vaccine product that holds neither an Emergency Use Listing (EUL) by the World Health Organization (WHO) nor an EUA nor approval by the US Food and Drug Administration (FDA): Administer the first dose of Pfizer BioNTech COVID-19 vaccine according to the procedure described herein.
      2. One (1) previous dose of Pfizer BioNTech COVID-19 vaccine administered 21 or more days prior to the date of vaccine administration: Administer the second dose of Pfizer BioNTech COVID-19 vaccine according to the procedure described herein.
      3. An incomplete primary dose series of a COVID-19 vaccine product that holds an EUL by the WHO but does not hold an EUA by the FDA (e.g., only the first dose of a two-dose primary series) with the most recent dose 28 or more days prior to the date of vaccine administration: administer one dose of the Pfizer-BioNTech COVID-19 vaccine to complete the primary series.
      4. First booster dose
         1. A complete two (2) dose primary series of an mRNA (Pfizer-BioNTech or Moderna) COVID-19 vaccine or of a complete primary series of COVID-19 vaccines listed for emergency use by the World Health Organization (WHO) – either as a homologous (same vaccine for both doses) or heterologous (mix and max) series – with the final dose received at least five (5) months prior to the date of vaccine administration: Administer a first booster dose of Pfizer-BioNTech COVID-19 vaccine.
         2. An initial dose of Janssen/Johnson & Johnson COVID-19 vaccine at least two (2) months prior to the date of vaccine administration: Administer a first booster dose of Pfizer-BioNTech COVID-19 vaccine.
      5. Second booster dose:
         1. Age 50 years or older with receipt of a complete primary series of COVID-19 vaccines as described in this section and one (1) booster dose of any authorized or approved COVID-19 vaccine at least four (4) months before the date of vaccine administration: Administer a second booster dose of Pfizer-BioNTech COVID-19 vaccine.
         2. Age 18 years or older with receipt of a primary dose of Janssen (Johnson & Johnson) COVID-19 vaccine and a booster dose of Janssen (Johnson & Johnson) COVID-19 vaccine at least 4 months before the date of vaccine administration: Administer a second booster dose of Pfizer-BioNTech COVID-19 vaccine.
3. Screen for contraindications and precautions
   1. **Contraindications:** Do not administer the Pfizer-BioNTech COVID-19 vaccine to anyone with a known history of:
      1. a severe allergic reaction (e.g., anaphylaxis) to a prior dose of an mRNA COVID-19 vaccine (i.e., Moderna or Pfizer-BioNTech COVID-19 vaccines) or
      2. diagnosed allergy to any vaccine component (including polyethylene glycol) listed in the prescribing information at <https://www.fda.gov/media/144413/download>.
   2. **Precautions:**
      1. Defer administering the Pfizer-BioNTech COVID-19 vaccine to people who are moderately to severely ill with an acute illness until they have recovered.
      2. Defer administering the Pfizer-BioNTech COVID-19 vaccine to people with known current SARS-CoV-2 infection at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.
      3. Consider deferral of vaccination of persons with history of immediate (within 4 hours after vaccination) non-severe allergic reaction to a previous dose of any COVID-19 vaccine pending consultation with an allergist-immunologist.
      4. Consider deferral of vaccination of persons with a history of an immediate allergic reaction to a non-COVID-19 vaccine or injectable therapy that contains multiple components, one or more of which is a component of the Pfizer-BioNTech COVID-19 vaccine (excluding subcutaneous immunotherapy for allergies, i.e. “allergy shots”) pending consultation with an allergist-immunologist.
         1. This does not apply to persons with allergies unrelated to vaccines or injectable therapy (e.g., oral medications, animals, insects, venom, environmental, food, latex, etc.)
      5. History of myocarditis or pericarditis:
         1. Onset after receiving a previous dose of an mRNA COVID-19 vaccine: Defer administration of additional doses of mRNA COVID-19 vaccine. Administration of additional doses of mRNA COVID-19 vaccine can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions>
         2. Onset prior to COVID-19 vaccination: Defer administration of mRNA COVID-19 vaccine until after the episode of myocarditis or pericarditis has completely resolved. After resolution of episode, may receive any FDA-approved or -authorized COVID-19 vaccine.
      6. History of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A)
         1. Onset before receiving a first dose of COVID-19 vaccine: Defer administration of COVID-19 vaccine until clinical recovery has been achieved as assessed by the vaccine recipient’s treating team, including return to normal cardiac function, and until at least 90 days after their MIS-C or MIS-A diagnosis. [Insert the Organization’s procedure to refer these individuals for further evaluation and management].
         2. Onset after receiving a previous dose of any COVID-19 vaccine:
            1. If onset occurred 90 or more days after the date of the most recent COVID-19 vaccine dose, defer administration of COVID-19 vaccine until

clinical recovery has been achieved as assessed by the vaccine recipient’s treating team, including return to normal cardiac function,

at least 90 days after their MIS-C or MIS-A diagnosis.

the patient resides in an area where the COVID-19 community level is high or is otherwise at increased risk for exposure to SARS-CoV-2 (e.g., through occupation, travel, large gatherings).

Refer vaccine recipients who meet these criteria to medical evaluation for assessment [Insert the Organization’s procedure to refer these individuals for further evaluation and management].

COVID-19 vaccination may also be considered for children and adolescents who had MIS-C and do not meet all three criteria, at the discretion of their clinical care team (see [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#:~:text=19%20vaccination.-,Consultation%20for%20decisions%20about%20COVID%2D19%20vaccination,-A%20conversation%20between](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html%23:~:text=19%20vaccination.-,Consultation%20for%20decisions%20about%20COVID%2D19%20vaccination,-A%20conversation%20between)). Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination.

* + - * 1. If onset occurred fewer than 90 days after the date of the most recent COVID-19 vaccine dose, defer administration of subsequent doses of COVID-19 vaccine until additional data are available.
    1. The following people with contraindications to Janssen COVID-19 vaccines have precautions to the Pfizer-BioNTech COVID-19 vaccine. However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the [Clinical Immunization Safety Assessment COVIDvax project](https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html). Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. If a patient should present under this scenario, [Insert the Organization’s procedure to refer these individuals for further evaluation and management].
       1. Persons with a history of severe allergic reaction to the Janssen COVID-19 vaccine due to potential cross-reactive hypersensitivity between ingredients in the Janssen and Pfizer COVID-19 vaccines, and
       2. Persons with a history of immediate allergic reaction of any severity to polysorbate due to potential cross-reactive hypersensitivity between polysorbate and ingredients in the Pfizer-BioNTech COVID-19 vaccine.

1. Provide information on the Pfizer-BioNTech COVID-19 vaccine and obtain consent.
2. Prior to vaccine administration:
3. Inform each patient or a patient’s legal guardian, as applicable, of the risks, benefits, and alternatives of receiving the COVID-19 vaccine.

* As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, including: **(1)** FDA has authorized the emergency use of the adolescent and adult formulation of Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and up; **(2)** The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine; **(3)** The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown; and **(4)** Information about available alternative vaccines and the risks and benefits of those alternatives.

1. Provide each patient or patient’s legal guardian, as applicable, a copy of the “Fact Sheet for Recipients and Caregivers,” or direct the individual to <https://www.fda.gov/media/144414/download> to obtain the Fact Sheet.
2. Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. For more information, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).
3. Obtain verbal consent to administer the vaccine from the patient or the patient’s legal guardian, as applicable. [Insert how the Organization will be documenting consent and what forms will be used].
4. Provide necessary information on receiving the next dose of vaccine.
5. When administering the first dose of Pfizer-BioNTech COVID-19 vaccine, provide a vaccination card to the recipient or their caregiver with the location and date indicating when the recipient needs to return for the next dose of Pfizer-BioNTech COVID-19 Vaccine.
6. Storage and Handling of Vaccine
7. Pfizer-BioNTech COVID-19 vaccines contain preservative-free frozen suspension that must be stored at appropriate temperatures to preserve efficacy. Consult CDC, NYSDOH and Pfizer guidance on storage and handling of Pfizer-BioNTech COVID-19 vaccines.
8. Pfizer-BioNTech COVID-19 **gray cap** vaccine vials must be thawed prior to first puncture. Only thaw the number of vials that you believe you will need. Thawed vials cannot be refrozen. Each multi-dose vial contains enough suspension for six patients.
9. Thawing under refrigeration: A full carton of 10 vials may take up to 6 hours to thaw in the refrigerator. A smaller number of vials will thaw in less time.
10. Thawing at room temperature: Vials will thaw at room temperature (up to 25 ⁰C [77 ⁰F]) in 30 minutes. Unpunctured vials may be stored at room temperature for no more than a total of 12 hours.
11. After first puncture, doses must be used within 12 hours after which any remaining doses must be discarded.
12. Prepare to administer vaccine
13. Carefully inspect the vial prior to vaccine preparation. Confirm that the vial has a **gray cap** and is labeled “DO NOT DILUTE” and for ages 12 years and older. If the vial has a purple cap, then consult the standing orders for Pfizer-BioNTech purple cap vaccine vials for vaccine preparation instructions.
14. Pfizer-BioNTech COVID-19 vaccine vials do not contain preservatives. Strict adherence of aseptic technique during dilution and administration must be followed.
15. Ensure the vaccine vial has thawed to room temperature prior to first puncture. If a vial feels cold to the touch, then it has not thawed enough.
16. Gently invert the vaccine vial ten (10) times to mix. Do not shake. Shaking can impair the efficacy of the vaccine.
17. Inspect the liquid in the vial. Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles. After mixing, the vaccine should appear as a white to off-white suspension with no visible particles. Do not use if liquid is discolored or if particles are observed after mixing.
18. **Do not dilute** Pfizer-BioNTech vaccine vials with gray caps labeled “DO NOT DILUTE”.
19. Visually assess patient weight and select a needle for vaccine administration based on the following chart:

|  |  |  |
| --- | --- | --- |
| Patient Gender | Patient Weight | Needle Length |
| Female | < 130 lbs | 5/8\* – 1” |
| 130–152 lbs | 1" |
| 153–200 lbs | 1–1½" |
| 200+ lbs | 1½" |
| Male | < 130 lbs | 5/8\* – 1” |
| 130–152 lbs | 1" |
| 153–260 lbs | 1–1½" |
| 260+ lbs | 1½" |

\*Some experts recommend a 5/8-inch needle for vaccine recipients who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

1. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine.
2. Administer vaccine
3. Visually inspect each dose in the dosing syringe prior to administration.
   1. Verify the final dosing volume of 0.3 mL.
   2. Confirm there are no particulates and that no discoloration is observed.
   3. Do not administer if vaccine is discolored or contains particulate matter.
   4. Call the manufacturer and the NYSDOH if the vaccine is discolored or contains particulate matter.
4. Administer the Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL, in the deltoid muscle via the intramuscular (IM) route.
5. Document vaccination

Document each patient’s vaccine administration information and follow-up in the following places:

**Medical Record System (including CDMS, as applicable):** Ensure that the patient’s name, the date the vaccine was administered, the name of the vaccine, the manufacturer and lot number, the vaccination site and route, address of administering site, and the name and title of the authorized vaccinator administering the vaccine, the publication date of the EUA fact sheet and the date it was given to the patient is documented in the patient’s medical record or on a separate form retained by the authorized vaccinator who has administered the immunization, and in a retrievable format available to the State Education Department and the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, refusal). Documentation must be completed within 24 hours of administration. This information, whether in a medical record or separately kept, must be recorded and maintained in accordance with 8 NYCRR section 29.2 (a) (3).

**Signed Certificate of Immunization** (given to the patient)**:** Record the patient’s name, date of vaccination, name/location of the administering clinic, administering vaccinator, name of vaccine, manufacturer and lot number, and recommendations for future immunizations.

**New York State Immunization Information System (NYSIIS) and City Immunization Registry (CIR):** Report all doses administered to NYSIIS or CIR within 24 hours of administration. [If using CDMS] With respect to NYSIIS, if the dose was documented in CDMS, then the NYSDOH shall transmit data from CDMS to NYSIIS for all patients.

1. Authorized vaccinators must inform vaccine recipients age less than 18 years and the adult caregiver accompanying such patient of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.
2. Management of medical emergencies

Observe all patients for the following observation periods following vaccination to monitor for the occurrence of immediate adverse reactions:

* 30 minutes:
  + People with a contraindication to Janssen COVID-19 vaccine who receive Pfizer-BioNTech COVID-19 vaccine,
  + History of non-severe, immediate (less than 4 hours) allergic reaction after a previous dose of COVID-19 vaccine,
  + History of an immediate allergic reaction of any severity to a vaccine or injectable therapy, and
  + History of anaphylaxis due to any cause.
* 15 minutes: All other people.

Be prepared for management of a medical emergency related to the administration of vaccine by maintaining written copies of the standing orders and protocols for administration of epinephrine and diphenhydramine. RNs shall be responsible for having emergency anaphylaxis treatment agents, related syringes and needles at the immunization site, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and a stethoscope and timing device to assess pulse. To prevent syncope, vaccinate patients while they are seated or lying down and assess for signs of syncope such as extreme paleness, sweating, coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness or visual disturbances.

For more information, please see:

* Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination sites at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>
* CDC’s General Best Practice Guidelines for Immunization, “Preventing and Managing Adverse Reactions,” at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.pdf>
* Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Adults in a Community Setting” at <https://www.immunize.org/catg.d/p3082.pdf>.
* Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Children and Teens in a Community Setting” at <https://www.immunize.org/catg.d/p3082a.pdf>.

1. Reporting of adverse events
2. Report the following information associated with the administration of Pfizer BioNTech COVID‑19 vaccine of which they become aware to Vaccine Adverse Events Electronic Reporting System (VAERS) in accordance with the “Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers),” including:
3. Vaccine administration errors whether or not associated with an adverse event
4. Serious adverse events (irrespective of attribution to vaccination)[[1]](#footnote-1)
5. Cases of Multisystem Inflammatory Syndrome in children and adults
6. Cases of COVID-19 that result in hospitalization or death
7. Any additional adverse events and revised safety requirements per the Food and Drug Administration’s conditions for use of an authorized vaccine throughout the duration of the EUA.
8. Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The VAERS reports should include the words “Pfizer-BioNTech COVID‑19 Vaccine EUA” in the description section of the report. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.
9. Conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

**Order:** I am hereby prescribing this non patient-specific order for the administration of Pfizer-BioNTech COVID‑19 Vaccine to persons age 12 years or older on [insert dates and locations].Specifically, [insert staff titles] who are employees, volunteers, or contractors of the [Insert Organization] may administer the Pfizer-BioNTech COVID‑19 Vaccine, as permitted by its Emergency Use Authorization (EUA), as applicable, state and federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness (PREP) Act declarations, ACIP recommendations, and the CDC’s and New York State’s Vaccination Program.

This non patient-specific order shall remain in effect for the vaccination of any individuals as set forth herein, beginning on [insert date] through [insert date]. In the event that I discontinue this non patient-specific order prior to [insert end date as listed above], notice of such discontinuance shall be provided to those [Insert Organization] employees and contractors permitted to execute under this Order via [insert how employees and contractors will be notified of a discontinuance].

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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NYS License No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Effective Date of Order: \_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Serious adverse events are defined as: (1) Death; (2) A life-threatening adverse event; (3) Inpatient hospitalization or prolongation of existing hospitalization; (4) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; (5) A congenital anomaly/birth defect; or (6) An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above. [↑](#footnote-ref-1)