

Consent for COVID-19 Vaccinations

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The Vaccine



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Emergency Use Authorizations (EUAs)

- Allows use of vaccines (and other medical products) that have not yet received full FDA approval in certain emergency situations, including a public health emergency
- Applications for EUAs for COVID-19 vaccines must include safety and efficacy data from trials with participants who received either vaccine or placebo
 - Safety: Side effects (e.g., sore arms, minor symptoms) and adverse events (e.g., serious allergic reaction)
 - Efficacy: Incidence of illness, serious illness/hospitalization, and death from COVID-19 in vaccinated group vs. placebo group



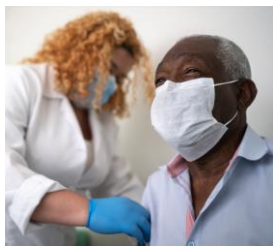
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EUAs as of 2/26/2021

Product	EUA Date	Dosage	Age Groups
Pfizer	December 11, 2020	2 doses 21 days apart	16 and older
Moderna	December 18, 2020	2 doses 28 days apart	18 and older
Johnson & Johnson	In progress: <ul style="list-style-type: none"> February 4: Application submitted February 26: FDA meeting If FDA endorses, CDC meeting will follow promptly and EUA may issue shortly after that 	1 dose	Expected to be 18 and older

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Vaccination



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You have a spot, take your shot. A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. To save lives and slow the spread of COVID-19, independent state and federal public health advisory committees recommend first protecting health care workers, people who are at the highest risk of being hospitalized or dying, and those at high risk of exposure to COVID-19. Keep practicing the 3 Ws—wear a mask, wait six feet apart, wash your hands—until everyone has a chance to get vaccinated.

- 1 Health Care Workers and Long-term Care Staff and Residents** ACTIVE GROUP
- 2 Older Adults** ACTIVE GROUP
- 3 Frontline Essential Workers** Feb. 24: Active for child care & preK-12 education
Mar. 10: Active for all others in this group
- 4 Adults at High Risk for Exposure and Increased Risk of Severe Illness**
- 5 Everyone**

Our goal is to vaccinate as many people as quickly as possible given the limited supply of vaccines. North Carolina moves through vaccination groups by aligning to federal priorities while empowering local health departments and hospitals with flexibility to move to the next priority group as they complete groups and have vaccines available.

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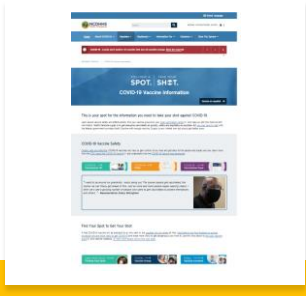
More information

North Carolina COVID-19 Vaccination website: YourSpotYourShot.nc.gov

Tools:

- Find My Vaccine Group
- Find a Vaccine Location

Other Resources: FAQs, flyers, guidance documents, data, etc.



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Consent to Vaccination



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General rules: Adults (age 18+)

- Adults may consent for themselves unless they lack capacity to consent
- Adults who cannot make or communicate health care decisions need a substitute decision-maker
- G.S. 90-21.13 specifies substitute decision-makers in priority order:
 - Health care agent appointed in valid health care POA, to the extent POA allows and unless suspended by court in accordance with G.S. 35A-1208(a)
 - Guardian of the person or general guardian appointed pursuant to G.S. Ch. 35A, Art. 5
 - Other health care agent appointed by the patient
 - Patient's spouse
 - Majority of patient's reasonably available parents and children age 18+
 - Majority of patient's reasonably available siblings age 18+
 - Individual with established relationship with the patient who is acting in good faith on behalf of the patient and can reliably convey patient's wishes

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General rules: Emancipated minors

- Emancipated minor (G.S. Ch. 7B Art. 35):
 - Married (age 14+)
 - Court order of emancipation (age 16+)
- Emancipated minors may consent for themselves unless they lack capacity to consent. G.S. 90-21.5(b).
- An emancipated minor who cannot make or communicate health care decisions needs a substitute decision-maker. See G.S. 90-21.13.

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Unemancipated minors (< 18)

- General rule: Unemancipated minors need consent of parent, guardian, or person standing in loco parentis. See, e.g., Adams v. Tessenier, 354 N.C. 57 (2001) (discussing fundamental right of parents to care, custody, and control of child); see also G.S. 7B-3400; 90-21.1.
- Exceptions:
 - Emergency/urgent circumstances in which parent's consent cannot reasonably be obtained during the time treatment is needed. G.S. 90-21.1.
 - Parent executes a type of POA that authorizes another to consent to treatment for the minor. G.S. Ch. 32A Art. 4.
 - Minor may give effective consent for certain medical health services, **including services for the prevention of reportable communicable disease**. G.S. 90-21.5
- **Special rule for immunizations:** A physician or local health department may immunize a minor who is presented for immunization by an adult who attests in writing that the minor's parent has authorized the adult to obtain the immunization. G.S. 130A-153(d).

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What varies based on who presents an unemancipated minor for vaccination?

Parent/Legal Guardian

- Will be asked if they consent and can affirm orally
- Issue: Children for whom consent is given by an adult acting in loco parentis

Another adult (person 18+) authorized by the parent to take the child for vaccination

- Does not have to have POA or writing of any kind from parent, but must attest in writing that they have the parent's permission to get the child vaccinated
- Issue: Some clinics presently not set up to accept and retain written documents

Minor

- May be able to give effective consent under minor's consent law, if the minor has *decisional capacity* (also known as "competence to consent")
- Will be asked if they consent and can affirm orally

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Is COVID-19 vaccination routine?

- No clear answer
- One hand:
 - Recommendations of CDC Advisory Committee on Immunization Practices (ACIP) already endorse COVID-19 vaccination for patients age 16+
 - Expected that ACIP will endorse for younger patients, if/when clinical trials demonstrate safety and efficacy and FDA authorizes use in these age groups
- Other hand:
 - Initial products will be under EUAs
 - COVID-19 vaccination is not part of the "standard schedule of immunizations" in North Carolina

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Summary: COVID-19 vaccinations for minors (under age 18) in DSS custody

Eligibility for vaccination

- Presently ages 16+ only; expect this to change as clinical trials conclude
- Phased rollout of vaccinations underway; whether there will be pediatric-specific adjustments is TBD

Minor's consent to vaccination

- G.S. 90-21.5 likely authorizes minors with decisional capacity to consent
- No distinction among minors based on living situation: with parent, in foster care, etc.

DSS director consent under G.S. 78-505.12

- Unclear whether COVID-19 vaccination is "routine" care
- Prudent to proceed under subsection (c) if parent has known religious objections to other immunizations

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Foster Care 18-21 Program

Consent

- Adults for this purpose
- May consent on their own unless they lack capacity to do so
- If substitute decision-maker needed, see G.S. 90-21.13

Eligibility for vaccination

- Will be in accordance with state priority groups
- To determine group, consider employment, group living, and medical conditions
- See "Find Your Group" tool on YourShotYourSpot.nc.gov

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Questions?

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