Consent for COVID-19 Vaccinations

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1

The Vaccine



2

- Allows use of vaccines (and other medical products) that have not yet received full FDA approval in certain emergency stuations, 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

EUA application

FDA advisory committee

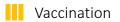
CDC advisory committee
(ACIP)

FDA issues
EUA

EUAs as of 2/26/2021

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: 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

4





5

To save lives and sic health care workers	ke your shot. A tested, safe and effective vaccine will ow the spread of COVID-19, independent state and fe i, people who are at the highest risk of being hospita —wear a mask, wait six feet apart, wash your hands—	deral public health advisory committees recon ized or dying, and those at high risk of exposu	mend first protecting
1 Health Ca	are Workers and Long-term Care Staff and	i Residents	ACTIVE GROUP
2 Old	der 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	n
	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 moves through vaccination groups by aligning to hospitals with flexibility to move to the next prior	federal priorities while empowering local healt	h departments and

WHO: FRONTLINE ESSENTIAL WORKERS

- Frontline essential workers are people who:

 Must be in-person at their place of work

 Work in one of the eight essential sectors listed below*

Higher proportion of chronic disease
High risk of exposure
Higher proportion of historically marginalized

populations				
Food & Agriculture	Government and Community Services	Health Care and Public Health	Public Safety	Transportation
ncluding for example: Meat packing workers Food processing workers Farmworkers Migrant farm/fishery workers Food distribution and supply chain workers Restaurant	Including for example: U.S. Postal Service Workers and other shipping workers Court workers - Clergy - Homeless shelter staff	Including for example: Public health workers Social workers	Including for example: Firefighters and EMS Law enforcement Corrections workers Security officers Public agency workers responding to abuse and needer!	Including for example: Public transit workers Division of Motor Vehicles workers Transportation maintenance and repair technicians Workers supporting his hower

*The frontline essential sectors and workers, as categorized by <u>Cybersecurity and Infrastructure Security Agency (CISA)</u> align with federal prioritization guidance from the CDC's Advisory Committee on Immunization Practices (ACIP) recommendations.



7

Opening Group 3

- Eligibility dates
 February 24: Child care and teachers/staff for pre-K to 12
- March 10: Others who meet criteria of in-person work plus essential industry

Eligibility for vaccination vs. availability of vaccine

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 Vaccine demand exceeds supply

 Being eligible <u>does not guarantee</u> a prompt appointment will be available

 Vaccine providers have flexibility

 May not provide appointments for Group 3 if still have long wait lists for Groups 1 or 2

 May prioritize within groups (e.g., by providing to older members of eligible group list)

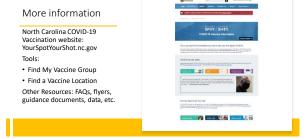
 May work with local schools or other essential employers to hold dedicated clinics for eligible workers

8

Group 4: Medical risk, group living, other essential workers

People with One or More Medical Conditions that Increase Risk of Severe Disease per CDC (as of 2/22/2021)			
Asthma (moderate to severe)	Heart conditions including coronary artery disease, heart failure, or cardiomyopathy		
Cancer	Hypertension		
Cerebrovascular disease	Immunocompromised		
Chronic kidney disease	Liver disease		
Chronic obstructive pulmonary disease	Overweight (BMI 25+) or obese (BMI 30+)		
Cystic fibrosis	Pregnancy		
Dementia and other neurological conditions	Pulmonary fibrosis		
Diabetes	Sickle cell disease		
Down syndrome	Smoking (current or former)		
	Thalassemia		
People Living in a Close Group Living Setting			
Anyone who is living in a congregate or close group living setting who is not already vaccinated (e.g., correctional facility, homeless shelter)			
Essential Workers Not Yet Vaccinated			
Those working in the essential industries identified in group 3 who did not meet the criteria for "frontline."			





Consent to Vaccination



General rules: Adults (age 18+)

- Adults may consent for themselves unless they lack capacity to consent
- G.S. 90-21.13 specifies substitute decision-makers in
- Health care agent appointed in valid health care POA, to the extent POA allows and unless suspended by court in accordance with G.S. SA-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

- 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 and can reliably convey patient's wishes

13

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.

14

Unemancipated minors (< 18)

- General rule: Unemancipated minors need consent of parent, guardian, or person standing in loco parentis. See, e.g., Adams v. Tessener, 354 N.C. 57 (2001) (discussing fundamental right of parents to care, custody, and control of child); see also 65.78-3400, 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.
 - true 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).

Consent for Juveniles in [OSS Nonsecure Custody		
(G.S. 7B-505.1)	,		
Subsection (a): Unless court orders otherw	vise, DSS director may arrange for, provide, or consent to:		
illnesses and injuries that require pro	 Routine medical and dental care or treatment, including treatment for common pediatric illnesses and injuries that require prompt intervention Emergency medical, surgical, psychiatric, psychological, or mental health care or treatment 		
Subsection (b) addresses child medical eva Subsection (c): Director shall obtain author	aluations.		
 Exception: Court may authorize directly clear and convincing evidence that 	, including immunizations when it is known that the n to the standard schedule of immunizations. torto provide consent after a hearing at which court finds the care, treatment, or evaluation requested is in the		
juvenile's best interest. • G.S. 7B-903.1(e): Provisions of 7B-505.1 a	pply to juveniles in custody pursuant to G.S. 7B-903		
16			
16			
Are immunizations generally	 No statutory definition of routine; no cases Subsection (c)'s requirement for parental authorization to the standard schedule of immunizations only when 		
considered routine medical care?	there is a known parental religious objection suggests that these are routine • The term is undefined but may refer to		
medical care:	immunizations required for school or child care. See G.S. 130A-155; 10A N.C.A.C. 41A, 0401 • A conclusion that immunizations are routine is consistent with health care provider guidelines for		
	assessing immunization status and offering immunizations as regular component of pediatric care • See, e.g., N.C. Pediatric Society, Fostering Health		
	NC Provider Guide (2016)		
		<u> </u>	
17			
Is COVID-19	No clear answer		
vaccination	One hand: Recommendations of CDC Advisory Committee on Immunization Practices (ACIP) already endorse COVID-19 vaccination for		
routine?	patients age 16+ Expected that ACIP will endorse for younger patients, if/when clinical trials demonstrate safety and efficacy and FDA authorizes use in		
	safety and efficacy and FDA authorizes use in these age groups Other hand: Initial products will be under EUAs	_	
	Initial products will be under EUAS COVID-19 vaccination is not part of the "standard schedule of immunizations" in North Carolina		
18			



DSS Form 1812

- To ensure children in DSS custody receive necessary care and treatment
- To ensure parents are engaged in children's care and treatment

To obtain parental authorization for DSS to consent to care or treatment that director lacks authority to consent to under G.S. 7B-505.1



19

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

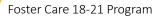
Minor's consent to vaccination

- 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.
- Consent under G.S. 7B-505.1? Three possibilities:
- . DSS director consent if routine care
- Form 1812 if:

 Routine but parent has religious objection

 Conclude that it is a procedure requiring informed consent, or that it is non-routine while under EUA

20



- Adults for this purpose
- $\bullet\,$ 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

Questions?

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