# SC BACK-TO-SCHOOL PARENT GUIDE

# Vaccinations, School and Your Doctor

UnitedParentsSC.org

*In the case of minor children, medical decisions are decided by the persons who hold the best interest of the child, which are parents or legal guardians. This Guide provides information on navigating the complexities of the health decision- making process, with a special focus on the risks and benefits of vaccinations.*

*This Guide is for educational purposes only, and not a substitute for professional medical advice.*

## WHO MAKES VACCINATION AND OTHER MEDICAL DECISIONS FOR CHILDREN IN SOUTH CAROLINA?

**In South Carolina the parent or legal guardian who is responsible for the child's health and safety makes the decisions on vaccinations and all other medical decisions for minor children under the age of sixteen[1].**

Public health officials at the South Carolina Health Department set vaccine school requirements, not the Center for Disease Control (CDC)[2]. Of the 16 CDC recommended childhood vaccinations[3], South Carolina school children are required to have various doses of 7 different vaccinations from pre-kindergarten to grade twelve, which include:

**Hepatitis B - DTaP- TDaP- Polio - MMR - Chicken Pox - Hepatitis A[4].**

In order for your child to attend South Carolina public or private schools*, parents or legal guardians are **required** to file your child's vaccination records or file a medical or religious vaccine exemption form at your child's school. South Carolina state law recognizes exemptions for required school vaccinations up-to grade twelve. [5]

Medical contraindications requiring a medical exemption are determined by a licensed medical provider. Religious exemptions are granted to students whose parent or legal guardian signs and has notarized the appropriate section (Statement of Religious Objection) of the South Carolina Certificate of Religious Exemption. The South Carolina Certificate of Religious Exemption may only be obtained at a county public health department. To learn more, go to: **scdhec.gov/exemptions-school-vaccine-requirements.**

## ABOUT YOUR MEDICAL PROVIDER

The overwhelming majority of medical providers are well-meaning individuals who hold the intention to make recommendations in the best interest of your child.

Due to past serious human rights violations,[6] [7] the importance of informed consent is continually highlighted throughout a medical provider's training to safeguard human rights and to ensure the ethical treatment of each individual in the healthcare setting. Informed consent also builds trust, which strengthens the doctor patient relationship.

## WHAT IS MEDICAL INFORMED CONSENT AND WHY IS IT IMPORTANT?

Vaccines, like all commercial pharmaceutical products carry two risks: a risk the vaccine product will fail to work[8] and a risk the vaccine product will cause harm[9].

- ✓ Informed Consent requires an objective disclosure of: the known or foreseeable benefits and risks of a particular intervention; knowledge gaps in safety and effectiveness; and alternative options to mitigate risk or provide benefit.
- ✓ An individual, parent or legal guardian is then provided the opportunity to make a voluntary decision to accept or decline that intervention.

**It is important to become informed about the potential complications of infectious diseases, as well as the potential complications of a vaccination, so you may be guided by knowledge in making a conscious choice on what you feel is the safest, healthiest choice for your individual child.**

- ✓ When you are asked to accept a vaccination on behalf of your child you may:

  1. proceed with getting your child vaccinated.
  2. decline getting your child vaccinated.
  3. neither be comfortable with either accepting nor declining a particular vaccination and have the option to do further research in order to make a more confident, informed decision.

---

[1] https://www.scstatehouse.gov/code/t44c066.php
[2] https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html
[3] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
[4] https://scdhec.gov/sites/default/files/media/document/Final-School-Law-Letter-2023-2024.pdf
[5] https://scdhec.gov/exemptions-school-vaccine-requirements *Private schools may not be required to accept vaccine exemptions. It is best to directly inquire about a school's policy.
[6] https://www.cdc.gov/tuskegee/timeline.htm
[7] https://history.nih.gov/display/history/Nuremberg%2BCode
[8] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949797/Greenbook_chapter_1_Jan21.pdf
[9] https://www.hrsa.gov/vaccine-compensation/covered-vaccines

## ABOUT MISINFORMATION

Misinformation is **incorrect** or **misleading** information**.** People, regardless of their education level or background, may be prone to believe misinformation because they are emotionally connected to what they are listening to or are reading. It is important to become informed so one may understand and be able to support, with data and evidence, why one is believing something.

## IF MY MEDICAL PROVIDER SUGGESTS THAT MY CHILD NEEDS TO BE UP TO DATE ON THE FLU, COVID-19, HPV OR OTHER VACCINES, DOES MY CHILD NEED THE VACCINE OR AN EXEMPTION TO ATTEND SCHOOL?

No. Only various doses of the **Hepatitis B, DTaP, TDaP, Polio, MMR, Chicken Pox** and **Hepatitis A** vaccines are required for school or require a medical or religious exemption. However, SC Department of Health Officials can add vaccines to the required school schedule at their discretion.[10]

## WHAT IF MY MEDICAL PROVIDER DISAGREES WITH ME FOR DELAYING OR DECLINING A REQUIRED OR RECOMMENDED VACCINATION FOR MY CHILD?

If you and your medical provider's viewpoints differ on what is best for your child, it is okay to agree to disagree.

If the conversation turns from respectful to difficult, it is okay to part ways and hire a medical provider who is more aligned with you on patient care. Coercion, fear or shame should never be employed to sway or manipulate anyone into accepting an intervention. Repeating talking points or using emotional arguments to persuade instead of directly addressing your questions, concerns or position is not in alignment with medical ethics or Informed Consent.

## HOW ARE VACCINES DIFFERENT THAN OTHER PHARMACEUTICALS YOUR MEDICAL PROVIDER MAY RECOMMEND?

Unlike other products in the United States (US), pharmaceutical companies manufacturing CDC recommended vaccines, as well as medical providers recommending and administering CDC recommended vaccines, are shielded from lawsuits if an infant, child or adult is injured or dies from a routine vaccination[11].

In 1986, Congress determined that vaccines have unavoidable, adverse side effects[12] and enacted the National Childhood Vaccine Injury Act (NCVIA)[13]. The NCVIA was created in response to costly lawsuits incurred by pharmaceutical companies from injuries and deaths caused by childhood vaccines and ensured industry will remain profitable and will continue to manufacture vaccines[14].

No other consumer products, including prescription and over the counter drugs, have liability-free status in the US.

## WHY ARE LIABILITY-FREE VACCINES MESSAGED AS "SAFE AND EFFECTIVE" IF THERE ARE POTENTIAL UNWANTED SIDE EFFECTS FOR MY CHILD?

When a vaccine is messaged as "safe and effective", it means the Food and Drug Administration (FDA) has made the decision that a vaccine will benefit most yet may cause what the FDA believes is an acceptable level of harm to some.

## WHY HAS THERE BEEN A GROWING NUMBER OF PARENTS QUESTIONING THE SAFTY OF VACCINATIONS?

In contrast to sound scientific practices, US federal health agencies take the position that conducting the most reliable safety testing, often referred to as "gold standard science"[15], would be unethical[16].

(Continued on page 4)

[10] https://scdhec.gov/sites/default/files/media/document/Final-School-Law-Letter-2023-2024.pdf
[11] https://www.congress.gov/bill/99th-congress/house-bill/5546
[12] https://supreme.justia.com/cases/federal/us/562/223/
[13] https://www.congress.gov/bill/99th-congress/house-bill/5546
[14] https://files.eric.ed.gov/fulltext/ED255480.pdf
[15] https://i-base.info/ttfa/8-clinical-trials-and-research/8-7-randomised-double-blind-placebo-controlled-trials/#:~:text=The%20most%20reliable%20evidence%20%E2%80%93%20often%20referred%20to,and%20in%20life%20%E2%80%93%20can%20happen%20by%20chance.
[16] https://www.cdc.gov/vaccinesafety/research/iomreports/index.html

This is because reliable clinical trial testing would require some children to receive injectable inert saline during a clinical trial rather than a routinely recommended vaccine or permit an unvaccinated control group in long-term scientific studies so the safety profile of the vaccine schedule can be better understood.

> *"…conducting a study requiring some children to receive fewer vaccines than recommended, as would be needed for a randomized controlled trial, would be unethical."*[17] –National Vaccine Advisory Committee (NVAC)

**In clinical research, inert placebo-controlled studies are the scientific standard due to inert controls like saline or sugar pill limiting research bias by having no effect on the human body[18].**

For example, the CDC recommends 19 injections of 8 vaccines to be routinely administered to infants by age 6 months[19]. In the majority of vaccine safety trials, placebo groups are vaccinated or have no control group. (see Table 1) Without a placebo controlled clinical trial, it is difficult to accurately assess the actual safety profile of each vaccine.

Table 1. Placebos used in clinical trials for FDA licensed, CDC recommended vaccines for infants on Day 1(birth) to 6 months*

| Infectious Disease | Vaccine Being Tested | "Placebo" Control Used in Clinical Trials (Instead of Injectable Saline) |
|---|---|---|
| **Diphtheria, Tetanus, Pertussis (DTaP)** *(3 doses)- 2, 4 & 6 months* | Infanrix[20] | **DTP Vaccine** |
| | Daptacel[21] | **DT or DTP Vaccines** |
| **Hepatitis B (Hep B)** *(3 doses)- Birth/day 1, 2 & 6 months* | Energerix-B[22] | **No Control Group** |
| | Recombivax HB[23] | **No Control Group** |
| **Hemphilus Influenza B (Hib)** *(3 doses)- 2, 4 & 6 months* | PedvaxHib[24] | **Lyophilized PedvaxHIB Vaccine** |
| | Hiberix[25] | **ActHIB Vaccine** |
| | ActHIB[26] | **Hepatitis B Vaccine** |
| **Polio (IPV)** *(3 doses)- 2, 4 & 6 months* | Ipol[27] | **No Control Group** |
| **Pneumococcal** *(3 doses)- 2, 4 & 6 months* | Prevnar 13[28] | **Prevnar Vaccine** |
| **Influenza** (Flu) *(1-2 doses)- annually beginning at 6 months* | FluLaval (IIV4)[29] | **Fluzone (IIV4) Vaccine** |
| **COVID-19** *(1-2 doses)- annually beginning at 6 months* | Bivalent Pfizer-BioNTech[30] | **^No safety testing was conducted on the Bivalent Vaccine for the 6-23 month age group.** |

***Rotavirus-** ***(2-3 doses) 2, 4 & 6 months.*** Rotavirus vaccines (Rotarix & RotaTeq)[31] were omitted from the table due to details of the placebo used in clinical trials not being disclosed in FDA documents. (Vaccines listed in the Table and Rotavirus = 8 vaccines)

**^**The FDA accepted Pfizer's position that the existing safety testing of the original Pfizer-BioNTech COVID-19 vaccine is relevant to the Pfizer-BioNTech's Bivalent COVID-19 vaccine for age 6-23 months, "because these vaccines are manufactured using the same process".[32]

**To see more complete Tables of the vaccines used as placebos in clinical trials for the CDC Childhood Vaccination Schedule and the length of safety review periods please click on the citation below.[33] To review adverse events experienced in vaccine clinical trials see the citation links below and go to Section 6 in each FDA document.**

[17] https://www.hhs.gov/sites/default/files/nvpo/nvac/meetings/pastmeetings/2009/nvacrecommendationsisoscientificagenda.pdf
[18] https://www.cdc.gov/vaccines/terms/glossary.html
[19] https://www.cdc.gov/vaccines/schedules/easy-to-read/child-easyread.html
[20] http://wayback.archive-it.org/7993/20170723024627/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244609.pdf **p6**
[21] https://www.fda.gov/media/74035/download
[22] https://www.fda.gov/media/79341/download
[23] https://www.fda.gov/media/74274/download
[24] https://www.fda.gov/media/80438/download
[25] https://www.fda.gov/media/77017/download
[26] https://www.fda.gov/media/74395/download
[27] https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/published/Package-Insert---IPOL.pdf
[28] http://labeling.pfizer.com/showlabeling.aspx?id=134
[29] https://www.fda.gov/media/115785/download
[30] https://www.fda.gov/media/167211/download **p27**
[31] https://www.fda.gov/media/75726/download Rotarix (GSK) https://www.fda.gov/media/75718/download RotaTeq (Merck)
[32] https://www.fda.gov/media/167211/download **p11**
[33] https://icandecide.org/wp-content/uploads/2019/09/ICAN-Reply-1.pdf **see Tables on p 4-6, p14 outlining vaccines used as "placebos" in clinical trials, safety review periods in clinical trials for recommended vaccines for age 2 months p 19-20**

## HAS THE US GOVERNMENT INVESTIGATED THE ADVERSE EVENTS FROM INDIVIDUAL VACCINES AND THE OVERALL CHILDHOOD VACCINATION SCHEDULE?

Yes. Throughout the years, the US government has commissioned the Institute of Medicine (IOM, now the National Academy of Medicine)[34] to conduct periodic reviews of the scientific literature and to publish reports on various aspects of the safety of the childhood vaccination schedule.

When Congress enacted the 1986 NCVIA, the recommended Childhood Vaccination Schedule was 11 doses of 4 vaccinations - DPT, Polio, MMR & Tetanus[35]. Today, the schedule has more than tripled[36] and there continues to be concerns related to the safety of the continually growing U.S. Childhood Vaccination Program.

Among some of the most recent scientific limitations in understanding the safety profile of vaccinations, the IOM pointed out the following:

- Of the 158 most common adverse events reported after vaccination, the scientific evidence was **inadequate to accept** or **reject** causation for 135 of the potential vaccine adverse events reported (80% of the conditions reviewed).[37]
- There is a **lack of quality scientific studies** to support the safety of the numbers of doses and timing of the overall CDC recommended vaccination schedule routinely administered to infants and children.[38] Yet, in the absence of quality scientific studies supporting the safety of the overall schedule, the IOM presumes safety:

  *"…based on the literature, the committee made a judgment that failed to link adverse effects to schedule exposures or multiple immunizations, concluding that there is no evidence that the schedule is not safe."*. [39]

**There continues to be fierce debate in the scientific and public arenas as to which is more unethical:**

1) A child not receiving a recommended vaccination while participating in a clinical trial or other studies evaluating the safety of an individual vaccine or the overall vaccination schedule, or

2) The government not permitting the use of the best available scientific methods by using inert placebos and unvaccinated controls so we may better understand of the safety profile of individual vaccines and the overall vaccination schedule routinely given to millions of US infants and children.

## WHAT IF MY CHILD EXPERIENCES AN ADVERSE EVENT AFTER BEING VACCINATED?

If an adverse event occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event, healthcare providers and parents are strongly encouraged to report to the online Vaccine Adverse Event Reporting System (VAERS)[40] and to get your child help.

VAERS is a national early warning system to detect possible safety problems in vaccines used in the United States. VAERS accepts and analyzes reports of adverse events (AEs) after a person has received a vaccination. For more information go to: **vears.hhs.gov/report event.html**

## WHY HAVE MEDICAL PROVIDERS, GOVERNMENT HEALTH OFFICIALS AND CONGRESS NOT INSISTED ON THE INNOVATION OF SAFER PRODUCTS THAT DO NOT REQUIRE LIABILITY-FREE STATUS?

This conversation is best had with the medical provider who is recommending vaccinations to your child, South Carolina public health officials who set vaccine requirements, and/or your state and federal elected officials.

Ethical considerations around vaccine research and policy are continually debated. However, government public health officials setting vaccination policies that medical providers are expected to follow often take the position that the basic goal of vaccination policies is to benefit the community at large rather than the individual[41].

[34] http://www.nasonline.org/about-nas/policy-studies-and-reports/
[35] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg
[36] https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
[37] https://www.nationalacademies.org/our-work/review-of-adverse-effects-of-vaccines **2011** https://pubmed.ncbi.nlm.nih.gov/25144097/ **1994** https://pubmed.ncbi.nlm.nih.gov/25121241/**1991**
[38] https://nap.nationalacademies.org/catalog/13563/the-childhood-immunization-schedule-and-safety-stakeholder-concerns-scientific-evidence **2013 IOM Review of Scientific Findings/Conclusions -p94**
[39] https://nap.nationalacademies.org/catalog/13563/the-childhood-immunization-schedule-and-safety-stakeholder-concerns-scientific-evidence **2013 IOM Conclusions/Recommendations p127**
[40] https://vaers.hhs.gov/reportevent.html
[41] https://www.nature.com/articles/ni0504-465