

US Vaccines Pregnancy Registry

CONSENT FOR GSK PREGNANCY REGISTRY

About your participation in a GSK pregnancy registry

The information around the use of vaccines in pregnant women is oftentimes limited. In order to gather data on the use of its vaccines in pregnant women, GlaxoSmithKline has put in place pregnancy registries for several of its vaccines. The information gathered from a pregnancy registry is aimed to help GSK gather valuable information about the safety of receiving specific GSK vaccines during pregnancy or within 28 days prior to conception.

If you are pregnant and have received a GSK vaccine with an established pregnancy registry, GSK would like to obtain information about your pregnancy and the health of your infant. For this, we ask your consent to contact your healthcare provider ("HCP") during your pregnancy and your child's HCP for up to a year after delivery.

About the information to be collected

It is very important that the personal and medical information shared with GlaxoSmithKline stay confidential and secure. GlaxoSmithKline will protect this information in accordance with current law. The name and identifying information of the participants will be entered into a database with restricted access to authorized personnel only. Customarily, participants are not identified by name in reports to regulatory agencies.

When you sign this consent form you agree that GlaxoSmithKline can:

- a) use your personal and medical information in order to contact you, your HCP and/or the HCP of your infant to obtain further information relating to your health, the pregnancy and/or the health of your infant, and to share it with regulatory agencies that monitor the safety of pharmaceutical and consumer products;
b) store and use, for as long as such information is legally required to be held, the personal and medical information of participants both in the country where you live or any other country in which GlaxoSmithKline has facilities. As a result, use of this information may take place in countries with lower data protection rules than the country you live in. GlaxoSmithKline will make sure that if your data is moved to another country, it will still be treated as stated in this Consent Form and, other than required by law, will remain confidential.
c) make the personal and medical information of participants available to third parties engaged to provide and support the services that GSK uses to process such information in order to meet its legal and regulatory obligations. GSK takes steps to ensure that these service providers protect the confidentiality and security of such personal and medical information, and to ensure that such information is processed only for the provision of the relevant services to GSK and in compliance with applicable law.

At any time, you may ask to see your personal information and correct it if necessary. Please contact us at the address provided. Participation in this pregnancy registry is completely voluntary and you can cancel participation at any time by calling 1-888-825-5249. Your decision not to participate or to cancel your participation will not cause a change in your medical care. In the event that you do cancel, any information collected prior to your cancelation may still be used for pregnancy registry purposes.

Please sign below to grant GSK permission to contact you, your HCP and/or your child's HCP for further information and to use this information as outlined above. In addition, please fill in the details in the boxes below. Note: if your pregnancy results in multiple births, please use one form for each infant.

If you have any questions about your and/or your child's participation in this pregnancy registry, you can call the GSK Pregnancy Registries at 1-888-825-5249 to obtain additional information.

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

PRINT NAME (Participant or Legal Representative) \_\_\_\_\_

Relationship to Participant (if Legal Representative) \_\_\_\_\_

Trade name of GSK vaccine participant was exposed to during pregnancy or within 28 days preceding conception:	
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*To obtain authorization to contact you for registry purposes:*

<b>PLEASE FILL IN TO ALLOW GLAXOSMITHKLINE TO CONTACT <u>YOU</u></b>	
I .....(PRINT NAME) give GlaxoSmithKline permission to contact me to obtain information regarding my healthcare provider and/or my child's healthcare provider. My preferred method of contact is (please provide preferred contact details below):	
<input type="checkbox"/> Telephone	<input type="checkbox"/> Postal Mail

*To obtain information about your pregnancy and delivery:*

<b>PLEASE FILL IN TO ALLOW GLAXOSMITHKLINE TO CONTACT <u>YOUR HEALTHCARE PROVIDER</u></b>	
I .....(PRINT NAME) give GlaxoSmithKline permission to contact my healthcare provider to obtain information regarding my health and pregnancy. My healthcare provider's details are:	
_____	
<b>Name of Healthcare Provider (obstetrician or other licensed medical practitioner)</b> (Please print or attach business card)	
_____	
<b>Street address</b>	
_____	
<b>City, Postal code</b>	<b>Phone Number</b>
_____	_____

*To obtain information about your child's health for up to a year after delivery:*

<b>PLEASE FILL IN TO ALLOW GLAXOSMITHKLINE TO CONTACT <u>YOUR CHILD'S HEALTHCARE PROVIDER</u></b>	
I .....(PRINT NAME) give GlaxoSmithKline permission to contact my child's healthcare provider to obtain information regarding my child's health. The details about my child's healthcare provider are provided below. If the details about my child's healthcare provider are not available at the time I complete this form, I understand GlaxoSmithKline may contact me around my expected delivery date to obtain this information.	
_____	
<b>Initials of child</b>	
_____	
<b>Name of child's Healthcare Provider, if available (pediatrician or other licensed medical practitioner)</b> (Please print or attach business card)	
_____	
<b>Street address</b>	
_____	
<b>City, Postal code</b>	<b>Phone Number</b>
_____	_____

**Please send the completed form to GSK via:**

**Fax:** 1-919-287-2902

**Mail:** Global Clinical Safety and Pharmacovigilance Mailstop 5.3461  
GlaxoSmithKline  
PO Box 13398  
Research Triangle Park, NC 27709-9627