Compound	Protocol	V////A/A/////
V503	005-00	\$44

Allocation Number

Vaccination Report Card

(11 - 15 Years of Age)

Only the PARENT or GUARDIAN of the subject should complete this vaccination report card. Corrections to the vaccination report card by the parent or guardian should be dated and initialed by the parent or guardian.

The STUDY NURSE will enter the dates where needed.

Complete this card for 15 days after vaccination (until and return the card to the study site when it is complete.	rear
Study Personnel Telephone Number:	
Parent or Guardian's Comments:	
Study Site Personnel Comments:	

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TEMPERATURE MEASUREMENT

It is important that you take your child's temperature every day starting with the day of vaccination through Day 5.

Take your child's temperature orally and record this temperature in the appropriate box below.

Take your child's temperature in the evening whenever possible. If you need to take your child's temperature more than once during a day, record the highest temperature taken that day.

TAKE ORAL TEMPERATURE EACH DAY				
DATE (month/day/year)		ORALTEMPERATURE		
1				
2				
3				
4				
5				

I have reviewed this information.

Staff's initials:

Date:

INSTRUCTIONS FOR INJECTION SITE REACTIONS:

On the following pages entitled "Injection Site Reactions", please measure any **swelling** or **redness** AT THE INJECTION SITE.

Estimate the **size** of the reaction at its <u>largest</u> from edge to edge. Use the <u>ruler marks</u> along the bottom of the page.

Mark the box that best describes the size of the reaction:

1 if the greatest width is anywhere in the area marked 1 (Example A)

2 if the greatest width is anywhere in the area marked 2

3 if the greatest width is anywhere in the area marked 3 (Example B)

Over 3 if the greatest width is in any area marked with a number over 3.

Write in the number. (Example C)

If the reaction is wider than the area marked 7, write in 8.

On the following pages entitled "Injection Site Reactions", please estimate the severity of any pain or tenderness or other reactions AT THE INJECTION SITE.

Mark the box that best describes the severity of the reaction using the following definitions:

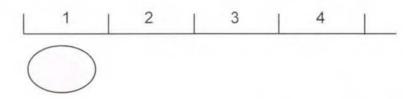
mild is awareness of symptom, but easily tolerated moderate is definitely acting like something is wrong severe is extremely distressed or unable to do usual activities

Complete one column each day, starting with Day 1 (the day of vaccination - 4 hours after injection). If the reaction continues past Day 5, please write in the last date it was present.

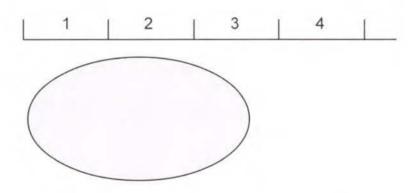
If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reactions".

EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

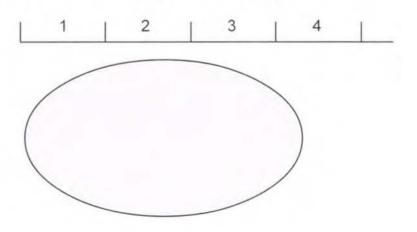
Example A: This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



Example B: This reaction falls in the area marked 3 at its largest, so you would check the box marked "3".



Example C: This reaction falls in the area marked 4 at its largest, so you would check the box marked "Over 3" and write in a 4.



		INJECT	ION SITE RE	ACTIONS		
Complete one c below.	opy of this page	per injection sit	e. Indicate the in	jection site for th	nis page by check	king one box
Injection Site (d	check one per p	age): □ Right	Arm □ Le	ft Arm	Right Thigh	☐ Left Thigh
		☐ Other				
	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	
	Vaccination Day		SAT 0	JAI 4	BATTO	REACTION PRESENT
	month/day/year	month/day/year	month/day/year	month/day/year	month/day/year	
SWELLING	□ None □ 1 □ 2 □ 3	□ None □ 1 □ 2 □ 3	□ None □ 1 □ 2 □ 3	□ None □ 1 □ 2 □ 3	□ None □ 1 □ 2 □ 3	month/day/year
	☐ over 3:	□ over 3:	□ over 3:	□ over 3:	□ over 3:	noter day your
REDNESS	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	month/day/year
					ī	
or TENDERNESS	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	□ None □ Mild □ Moderate □ Severe	□ None □ Mild □ Moderate □ Severe	□ None □ Mild □ Moderate □ Severe	month/day/year
THER INJECTION ITE REACTION Specify):	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	□ None □ Mild □ Moderate □ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	month/day/year
THER INJECTION ITE REACTION pecify):	☐ None ☐ Mild ☐ Moderate	☐ None ☐ Mild ☐ Moderate	□ None □ Mild □ Moderate	□ None □ Mild □ Moderate	□ None □ Mild □ Moderate	
	☐ Severe	☐ Severe	☐ Severe	☐ Severe	□ Severe	month/day/year
he date it starte njection site rea INJECTIOI	ed and the last	date it was pre	ys after your chi sent. Mark the DATE (month	box that best de	please record it scribes the seve	rity of the
	TER VACCINAT	SECTION .	Started	Last Present	0.11	rm3.4
					☐ mild ☐ mod	erate 🗆 severe
					☐ mild ☐ mod	erate 🗆 severe

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pelow.		per injection site age): ☐ Right	_	jection site for th	is page by check	king one box ☐ Left Thigh
		☐ Other				
	DAY 1 Vaccination Day	DAY 2	DAY 3	DAY 4	DAY 5	LAST DATE REACTION PRESENT
	month/day/year	month/day/year	month/day/year	month/day/year	month/day/year	
SWELLING	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	month/day/year
REDNESS	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	□ None □ 1 □ 2 □ 3 □ over 3:	montfv/døyi/year
PAIN or TENDERNESS	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	□ None □ Mild □ Moderate □ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	month/day/year
THER INJECTION ITE REACTION Specify):	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	□ None □ Mild □ Moderate □ Severe	□ None □ Mild □ Moderate □ Severe	month/day/year
THER INJECTION ITE REACTION specify):	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	month/day/year
	ed and the last				please record it escribes the seve	
BEGIN	N SITE REACT NING 6 OR MOI TER VACCINA	RE	DATE (month	h/day/year) Last Present	SEVE	RITY
					☐ mild ☐ mod	lerate 🗆 severe
					☐ mild ☐ mod	erate severe

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OTHER COMPLAINTS OR ILLNESSES

Record any other complaints or illnesses which developed or worsened during the 15 days after vaccination.

Record the date it started and the last date it was present.

Mark the box that best describes the severity of the complaint using the following definitions:

mild is awareness of symptom, but easily tolerated

moderate is definitely acting like something is wrong

severe is extremely distressed or unable to do usual activities

Do not record injection site complaints on this page. Those complaints are recorded on the previous page in the table entitled "Injection Site Reactions".

List each complaint or illness separately.

If during the 15 days after vaccination your child	did not have any other complaints or illnesses
check the box here: None	A STATE OF THE STA

OTHER COMPLAINTS	DATE (month/day/year)				
OR ILLNESSES	Started	Last Present	SEVERITY		
			□ mild □ moderate □ severe		
			☐ mild ☐ moderate ☐ severe		
		1	□ mild □ moderate □ severe		
			☐ mild ☐ moderate ☐ severe		
			☐ mild ☐ moderate ☐ severe		
			☐ mild ☐ moderate ☐ severe		
			☐ mild ☐ moderate ☐ severe		
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			☐ mild ☐ moderate ☐ severe		
			☐ mild ☐ moderate ☐ severe		
			☐ mild ☐ moderate ☐ severe		

		MED	ICATIONS		
Please list any Day 1	1	on or over the co hrough Day 15	unter medications y aft		akes starting from ld's injection.
LIST THE NAME MEDICATION		DATE: MEDICATION STARTIED (month/day/year)	DATE MEDICATION LAST TAKEN (month/day/year)		N FOR TAKING MEDICATION
		NON-STUD	Y VACCINATION:	s	
Record any va study vaccine	2		ing the 15 days a	fter your o	hild received th
LIST VACCINATION		SITE C	F VACCINATION		DATE RECEIVED (month/day/yea
	☐ Right Arm	☐ Left Arm ☐ Right	t Thigh	Other	
	☐ Right Arm	☐ Left Arm ☐ Righ	t Thigh	Other	

I confirm that the information on this card is accurate

☐ Left Thigh

(Date when follow-up is completed)

☐ Other

☐ Right Thigh

☐ Right Arm ☐ Left Arm

(Parent's Initials)