

### Form 205 – Annual Physical Exam

Selenium and Vitamin E Cancer Prevention Trial (S0000)				
<b>Form 205: Annual Physical Exam</b>				
<b>Participant ID</b>	<b>Ppt Initials (L, F, M)</b>	<b>Study Site #</b>	<b>Contact #</b>	<input type="checkbox"/> Check here if this form amends data submitted previously
<hr/>				
<b>Instructions:</b> Complete this form at each Annual Visit. The DRE and PSA are suggested procedures per Section 7.6 of the SELECT Protocol (S0000). If any part of this examination was not done at your Study Site, make sure you obtain source documentation, per Section 9 of the SELECT Study Manual.				
<hr/>				
<b>Date of Contact:</b>	<input type="text"/> <i>mm/dd/yyyy</i>	<b>Contact type:</b>	<input type="radio"/> Visit <input type="radio"/> Telephone	
<hr/>				
<b>1. Blood Pressure:</b>	<input type="text"/> mm/Hg	<input type="text"/> mm/Hg		
	Systolic	Diastolic		
<b>2. Weight (in kilograms):</b>	<input type="text"/> kg			
<hr/>				
<b>PROSTATE HEALTH</b>				
<b>3. Was a Total and/or Complex PSA done for this Annual Visit or since the last Annual Visit?</b>				
<input type="radio"/> No (Go to #4)				
<input type="radio"/> Yes				
<b>If Yes, specify most recent:</b>				
	<b>Date:</b>	<input type="text"/> <i>mm/dd/yyyy</i>		
	<b>Where done:</b>	<input type="radio"/> Study Site <input type="radio"/> Other		
	<b>Result:</b>	Total PSA	<input type="text"/> ng/ml <sup>†</sup>	
		Complex PSA	<input type="text"/> ng/ml <sup>†</sup>	

(Continued on the next page)

**Form 205 – Annual Physical Exam (continued)****4. Was a DRE done for this Annual Visit or since the last Annual Visit?**

- No (Go to #5a)  
 Yes

**If Yes, specify most recent:**

**Date:**   
*mm/dd/yyyy*

**Where done:**  Study Site  
 Other

**Result:**  Normal  
 Suspicious for cancer<sup>1</sup>

**SMOKING STATUS UPDATE****5a. Since his last Annual Visit, has the participant smoked any cigarettes?**

- No (Form complete)  
 Yes

**If Yes, on average how many per day when smoking?**

- 1-4       25-34  
 5-14      35-44  
 15-24     45 or more

**5b. Since his last Annual Visit, has the participant quit smoking?**

- No (Form complete)  
 Yes

**If Yes, approximate date quit:**

/  (mm/yyyy)

**Note:**

(1) See Section 7.7 of the SELECT Protocol (S0000) for management of participants with abnormal PSA and/or DRE.

**Comments:**


SUBMIT

(Version 2.0 - 02/20/04)

## Form 205 – Annual Physical Exam

<b>Submission:</b>	Web
<b>Completed by:</b>	Study Site Staff
<b>When to complete and submit:</b>	At each Annual Visit or Contact while the participant is On Supplements.
<b>Contact Number:</b>	020, 030, 040, 050, 060, 070, 080 (the following may be applicable depending on the time-point of the study when the participant was randomized) 090, 100, 110, 120, and 130

*\*Source documentation required.*

### Form Instructions:

Blood pressure and weight should be taken according to the Study Site's standard procedures; methods must be consistent each time these procedures are performed.

#### 2. Weight (in kilograms):

Record the participant's weight in kilograms using a leading zero if necessary.

**Formula for converting pounds into kilograms:**

$$\frac{\text{(Weight in pounds)}}{2.21} = \text{Weight in kilograms}$$

### PROSTATE HEALTH

The PSA and DRE in questions **3** and **4** include any procedure done since the last Annual Visit as well as any procedure done up to 42 days after this Annual Visit. For example, if a participant saw his primary care physician and had a DRE and PSA test done six months before this Annual Visit and has had no more recent procedures, include those DRE and PSA results here. Or, if a participant has a DRE and/or PSA test scheduled 4 weeks after the date of this Annual Visit, those results may be recorded for this Annual Visit. Any procedure more than 42 days after the Annual Visit date should be included on *Form 205 – Annual Physical Exam* for the next Annual Visit contact. Do not include the same procedure on multiple Annual Visits.

#### \*3. Was a Total and/or Complex PSA done for this Annual Visit or since the last Annual Visit?

If response is **Yes**, enter the following information to indicate the most recent:

**Date:** Enter the date the Total and/or Complex PSA was done. If a Total and Complex PSA were both done but on different dates, use only the results from the most recent test.

**Where Done:** Select **Study Site** or **Other** to indicate where the PSA was done.

**Result:** Enter the numeric result of the participant's most recent Total and/or Complex PSA as ng/ml. If the participant is taking finasteride, enter the unadjusted PSA. See [Section 7.7](#) of the SELECT Protocol (S0000) for management of participants with elevated PSA.

**\*4. Was a DRE done for this Annual Visit or since the last Annual Visit?**

If response is **Yes**, enter the following information to indicate the most recent:

**Date:** Enter the date the DRE was done.

**Where Done:** Select **Study Site** or **Other** to indicate where the DRE was done.

**Result:** Select **Normal** or **Suspicious for cancer** to indicate the result.

See [Section 7.7](#) of the SELECT Protocol (S0000) for management of participants with a DRE that was suspicious for cancer.

## SMOKING STATUS UPDATE

**5a. Since his last Annual Visit, has the participant smoked any cigarettes?**

If response is **Yes**, indicate the average number of cigarettes smoked per day while the participant was smoking.

**5b. Since his last Annual Visit, has the participant quit smoking?**

If response is **Yes**, indicate the month and year of the approximate date the participant quit smoking. Enter the date the participant quit smoking as Month/Year, using a leading zero if necessary for two-digit month. Enter four-digit year.