

INTRODUCTION TO FORM 47 – DEACTIVATION/OFF-STUDY FORM

Code 6 in Question B1 was used to indicate that the patient was deactivated due to the end of the study.

DEACTIVATION/OFF-STUDY FORM -- FORM 47 QxQ

Use this form if the patient is being deactivated, e.g., is being withdrawn from the VATS Study for any reason. Note that removal from study components and/or unblinding the patient is not a reason for going off-study. See protocol Section 7.2. In addition, missed visits do not constitute deactivation. Every attempt should be made to collect whatever data is available. This might involve searching medical records or corresponding with physicians, even in the absence of contact with the patient.

SECTION A -- GENERAL INFORMATION

- A1.** Affix the subject ID label. If label is not available, write the subject ID number in the space provided. If this is a multiple page form, affix an ID label or write the ID number on the top of each page in the space provided.
- A2.** Enter the visit number.
- A3.** Enter the subject's first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the subject does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box
- A5.** Record the date that this form is completed.
- A6.** Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person completing this form does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box.

SECTION B -- DEACTIVATION

- B1.** Check one box only, i.e., give the primary reason for deactivation. Complete a Death Report (Form 48) if the patient died, or the date last known to be alive, if the patient has been lost to follow-up. Otherwise, note the effective deactivation date at (a.). If a patient is deactivated due to a reason other than death, and the patient subsequently dies, complete a Death Report (Form 48) at the time of death.

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 47 -- DEACTIVATION/OFF-STUDY FORM**

SECTION A -- GENERAL INFORMATION

A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT)

____ - ____ - ____ - ____

FOR NERI / INTERNAL USE ONLY:

A2. LAST VISIT: ____

A3. Subject initials:

____. ____.

A4. Form version:

0 7 / 1 5 / 9 5

A5. Today's date:

____ / ____ / ____

A6. Initials of person completing form:

____. ____.

SECTION B -- DEACTIVATION

B1. Primary reason for deactivation/off-study:

1. Death

→ **COMPLETE FORM 48 -- DEATH REPORT.**

2. Lost to follow-up

→ a. Date last known to be alive:
____ / ____ / ____

3. Patient request

→ a. Deactivation date:
____ / ____ / ____

4. MD request

→ a. Deactivation date:
____ / ____ / ____

5. Other, Specify below ↓

→ a. Deactivation date:
____ / ____ / ____

END OF FORM

DEACTIVATION/OFF-STUDY FORM – FM47DATA CODEBOOK

PUB_ID ----- SUBJECT ID

type: numeric (float)
 range: [1,531] units: 1
 unique values: 529 coded missing: 0 / 529
 mean: 266.036
 std. dev: 153.318
 percentiles: 10% 25% 50% 75% 90%
 53 134 266 398 479

FORM_V ----- A4.FORM VERSION

type: numeric (float)
 label: FORM_V
 range: [12979,12979] units: 1
 unique values: 1 coded missing: 0 / 529
 tabulation: Freq. Numeric Label
 529 12979 07/15/95

COMP_D ----- A5.DATE FORM COMPLETED

type: numeric (float)
 range: [0,1413] units: 1
 unique values: 402 coded missing: 0 / 529
 mean: 509.423
 std. dev: 400.944
 percentiles: 10% 25% 50% 75% 90%
 53 136 424 839 1115

COMP_D:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).

REASON ----- B1.REASON FOR DEACTIVATION

type: numeric (float)
 label: REASON
 range: [1,6] units: 1
 unique values: 6 coded missing: 0 / 529
 tabulation: Freq. Numeric Label
 286 1 1:Death
 27 2 2:Lost to follow-up
 28 3 3:Patient request
 1 4 4:MD request
 6 5 5:Other
 181 6 6:End of study

LASTDATE ----- Bla.DEACT DATE OR LAST DATE KNOWN ALIVE

type: numeric (float)

range: [0,1380] units: 1

unique values: 199 coded missing: 286 / 529

mean: 715.601

std. dev: 393.806

percentiles: 10% 25% 50% 75% 90%

95 407 735 1079 1200

LASTDATE:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).

LASTDATZ ----- DATE IMPUTATION INDICATOR -- LASTDATE

type: numeric (float)

label: LASTDATZ

range: [1,2] units: 1

unique values: 2 coded missing: 0 / 529

tabulation:	Freq.	Numeric	Label
	528	1	Date not imputed
	1	2	15th of month imputed

LASTDATZ:

1. Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing.