Subject No. _____

An Open-Label, Randomized, Two-Period, Crossover Pivotal Study to Evaluate the Relative Bioavailability of an Extended-Release Test Formulation of Morphine Sulfate (120 mg Capsule) Compared to an Equivalent Dose of the Reference Listed Drug (Avinza® 120 mg, Ligand Pharmaceuticals Incorporated) in Normal Human Subjects Under Fed Conditions

Study # 850

CASE REPORT FORM

tyco / Healthcare / Mallinckrodt

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials
X X X	0	

INCLUSION/EXCLUSION CRITERIA

Did the subject meet all inclusion criteria? No ☐ Yes ☐ **[If No, note exception below]**

If a Sponsor-approved exception applies to any of the inclusion criteria, list the criterion number, comments, the name of the person who approved the exception, and the date the exception was granted.

Criterion Number	Comment	Approved by	Date (d d / m m m / y y y y)

Did the subject qualify for any exclusion criteria? No ☐ Yes ☐ **[If Yes, note exception below]**

If a Sponsor-approved exception applies to any of the exclusion criteria, list the criterion number, comments, the name of the person who approved the exception, and the date the exception was granted.

Criterion Number	Comment	Approved by	Date (d d / m m m / y y y y)

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Site	Subject Number	Subject Initials
X X X	0	

DEMOGRAPHICS

Date of Informed Consent: (d d / m m m / y y y y) 2 0

Time of Informed Consent: : (24 hr clock)

Ethnicity: ☐ Hispanic ☐ Non-Hispanic

Race:
- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black, of African heritage
- ☐ Native Hawaiian/Other Pacific Islander
- ☐ White

Birthdate:

Sex: ☐ Male ☐ Female

Body Mass Index (BMI):

Height: in

Weight: lb

MEDICAL AND SURGICAL HISTORY

Date obtained: 2 0 (d d / m m m / y y y y)

Is there a medical history or current abnormality/disease of the following systems?

Examination	No (X)	Yes (X)	If **Yes**, specify and provide onset date if known.
General	☐	☐	
Dermatological	☐	☐	
HEENT	☐	☐	
Respiratory	☐	☐	
Cardiovascular	☐	☐	
Gastrointestinal	☐	☐	
Genitourinary	☐	☐	
Gynecological	☐	☐	NA ☐
Endocrine	☐	☐	
Musculoskeletal	☐	☐	
Hematological	☐	☐	
Neuro-Psychological	☐	☐	

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254 MNKOI 0006877233

Subject Identification	STUDY # 850	Mallinckrodt Inc.
Site: X X X	Subject Number: 0	Subject Initials:

MEDICAL HISTORY: Allergies

Does the subject have a history of allergies?

No ☐ Yes ☐ If **Yes**, complete the following information:

Classification Codes: 1 = Food, 2 = Drug, 3 = Environmental

Classification (1, 2, or 3)	Allergen	Reaction

VITAL SIGNS : SCREENING

Observation Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	Blood Pressure (mmHg)		Pulse Rate (bpm)	Respiratory Rate (breaths/min)	Oxygen Saturation (%)	Temperature (F°)
			Systolic	Diastolic				
Screening	2 0	:						
Repeat Screening? No ☐ Yes ☐	2 0	:						

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Site	Subject Number	Subject Initials
X X X	0	

PHYSICAL EXAMINATION: Screening

Date and time of Exam: d d / m m m / y y y y : 24 hr clock

Are there any abnormalities of the following based on the examination?

Observations	No (X)	Yes (X)	Not Examined (X)	If **Yes**, briefly describe the abnormal findings:
General Appearance	☐	☐		
Skin	☐	☐	☐	
HEENT	☐	☐	☐	
Neck	☐	☐	☐	
Chest	☐	☐	☐	
Heart	☐	☐	☐	
Abdomen/Pelvis	☐	☐	☐	
Extremities	☐	☐	☐	
Neurological	☐	☐	☐	

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Site	Subject Number	Subject Initials
X X X	0	

ADDITIONAL LABORATORY DATA

Were any additional laboratory tests performed? No ☐ Yes ☐

If Yes, fill in date, time and reason for additional test(s) below:

Date of Sample (d d / m m m / y y y y)	Sample Time (24 hr clock)	Reason
	:	
	:	
	:	
	:	
	:	
	:	
	:	
	:	
	:	
	:	

If additional labs were drawn, attach lab reports to CRF

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.
Site: X X X	Subject Number: 0	Subject Initials:

PRIOR/CONCOMITANT MEDICATION/TREATMENT

Were any prescription medications/treatments taken within 14 days (within 7 days for over-the-counter medications) prior to Period 1 dosing through the Exit Exam? No ☐ Yes ☐

If Yes, please record below.

If the medication/treatment is continuing, indicate by recording an "X" in the box marked "Med Cont." (Note: "Indication" for any medications/treatments administered specifically for an adverse event should be listed as the adverse event for which it was prescribed.)

Medication/Treatment	Total Daily Dose (include units)	Route of Administration	Dosage Form	Indication	Event Number (for AE meds only)	Date (dd / mmm / yyyy)	Med Cont. (X)
						From / To	☐
						From / To	☐
						From / To	☐
						From / To	☐
						From / To	☐
						From / To	☐

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.
Site: X X X	Subject Number: 0	Subject Initials:

SUPPLEMENTAL PRIOR/CONCOMITANT MEDICATION/TREATMENT

If the medication/treatment is continuing, indicate by recording an "X" in the box marked "Med Cont." (Note: "Indication" for any medications/treatments administered specifically for an adverse event should be listed as the adverse event for which it was prescribed.)

Medication/Treatment	Total Daily Dose (include units)	Route of Administration	Dosage Form	Indication	Event Number (for AE meds only)	Date (dd / mmm / yyyy)	Med Cont. (X)
						From / To	☐
						From / To	☐
						From / To	☐
						From / To	☐
						From / To	☐
						From / To	☐
						From / To	☐

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.
Site: X X X	Subject Number: 0	Subject Initials:

ADVERSE EVENTS

Were adverse events noted during the time from the signing of the informed consent through the Period 2 Exit Exam?

No ☐ Yes ☐ If Yes, describe below.

Adverse Event (one per line)	Date and Time of Onset and Resolution		Is the Adverse Event Serious? 1 = No 2 = Yes	Severity 1 = Mild 2 = Moderate 3 = Severe	Corrective Treatment 1 = None 2 = Hospitalized 3 = Medication/ Treatment (specify on Con Med page)	Outcome 1 = Recovered 2 = Recovered w/sequelae* 3 = Ongoing 4 = Death 5 = Unknown*	Relationship to Study Drug 1 = Unrelated 2 = Unassessable 3 = Unlikely 4 = Likely
	Date (dd/mmm/yyyy)	Time (24 hr clock)					
1)	Onset	:					
	Resolution	:					
Comment:							
2)	Onset	:					
	Resolution	:					
Comment:							

* If appropriate, please comment.

Investigator's Signature

Date: (d d / m m m / y y y y)

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials
X X X	0	

SUPPLEMENTAL ADVERSE EVENTS

Adverse Event (one per line)	Date and Time of Onset and Resolution		Is the Adverse Event Serious? 1 = No 2 = Yes	Severity 1 = Mild 2 = Moderate 3 = Severe	Corrective Treatment 1 = None 2 = Hospitalized 3 = Medication/ Treatment (specify on Con Med page)	Outcome 1 = Recovered 2 = Recovered w/sequelae* 3 = Ongoing 4 = Death 5 = Unknown*	Relationship to Study Drug 1 = Unrelated 2 = Unassessable 3 = Unlikely 4 = Likely
	Date (dd/mmm/yyyy)	Time (24 hr clock)					
_)	Onset	:					
	Resolution	:					
Comment:							
_)	Onset	:					
	Resolution	:					
Comment:							

* If appropriate, please comment.

Investigator's Signature

Date: (d d / m m m / y y y y)

7

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Site	Subject Number	Subject Initials
X X X	0	

NALTREXONE DOSING: Period 1

Dosing Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	
12 hours prior to dosing	2 0	:	
12 hours post dosing	2 0	:	
24 hours post dosing	2 0	:	
36 hours post dosing		:	

Note: Time of 0 hr dosing is reflected on Blood Sample & Dose Log page.

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials	NOTE: Repeated out-of-range vital signs that do not return to normal values are considered AEs and should be documented on the Adverse Events page.
X X X	0		

VITAL SIGNS: Period 1

Observation Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	Blood Pressure (mmHg)		Pulse Rate (bpm)	Respiratory Rate (breaths/min)	Oxygen Saturation (%)
			Systolic	Diastolic			
12 hours pre-dose	2 0	:					
11 hours pre-dose		:					
Pre-dose	2 0	:					
1 hour post-dose		:					
1.5 hours post-dose		:					
2.5 hours post-dose		:					
4.5 hours post-dose		:					
6.5 hours post-dose		:					
8.5 hours post-dose		:					
10.5 hours post-dose		:					
12 hours post-dose		:					
13 hours post-dose		:					

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials	NOTE: Repeated out-of-range vital signs that do not return to normal values are considered AEs and should be documented on the Adverse Events page.
X X X	0		

VITAL SIGNS: Period 1 Continued

Observation Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	Blood Pressure (mmHg)		Pulse Rate (bpm)	Respiratory Rate (breaths/min)	Oxygen Saturation (%)
			Systolic	Diastolic			
14 hours post-dose	2 0	:					
16 hours post-dose	2 0	:					
24 hours post-dose	2 0	:					
25 hours post-dose	2 0	:					
36 hours post-dose		:					
37 hours post-dose	2 0	:					
48 hours post-dose	2 0	:					
60 hours post-dose		:					
72 hours post-dose	2 0	:					

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials	
X X X	0		**NOTE: Repeated out-of-range vital signs that do not return to normal values are considered AEs and should be documented on the Adverse Events page.**

Were any additional/repeat Vital Signs done during Period 1? No ☐ Yes ☐ If Yes, record below.

Observation Time Repeated	Date (d d / m m m / y y y y)	Time (24 hr clock)	Blood Pressure (mmHg)		Pulse Rate (bpm)	Respiratory Rate (breaths/min)	Oxygen Saturation (%)	Comments
			Systolic	Diastolic				
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials	
X X X	0		**NOTE: Repeated out-of-range vital signs that do not return to normal values are considered AEs and should be documented on the Adverse Events page.**

SUPPLEMENTAL ADDITIONAL/REPEAT VITAL SIGNS: Period 1

Observation Time Repeated	Date (d d / m m m / y y y y)	Time (24 hr clock)	Blood Pressure (mmHg)		Pulse Rate (bpm)	Respiratory Rate (breaths/min)	Oxygen Saturation (%)	Comments
			Systolic	Diastolic				
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials
X X X	0	

MEAL CONSUMPTION RECORD: Period 1

Did subject consume the entire breakfast?

☐ No (If No, the subject is to be dropped.)

☐ Yes

Breakfast Start Time: _ _ : _ _ (24 hr clock)

Breakfast End Time: _ _ : _ _ (24 hr clock)

BLOOD SAMPLE & DOSE LOG: Period 1

Treatment Assignment:

☐ Treatment A

☐ Treatment B

Dosing Date (d d / m m m / y y y y): _ _ _ _ _ 2 0 _ _

Time: _ _ : _ _ (24 hr clock)

Note: Dosing date and time will be for treatment dosing as well as 0 hour Naltrexone dosing.

Sampling Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	Comments
Pre-Dose	_ _ _ _ _ 2 0 _ _	_ _ : _ _	
0.75 hours post-dose		_ _ : _ _	
1.5 hours post-dose		_ _ : _ _	
2.5 hours post-dose		_ _ : _ _	
3.5 hours post-dose		_ _ : _ _	
4.5 hours post-dose		_ _ : _ _	
5.5 hours post-dose		_ _ : _ _	
6.5 hours post-dose		_ _ : _ _	
7.5 hours post-dose		_ _ : _ _	
8.5 hours post-dose		_ _ : _ _	
9.5 hours post-dose		_ _ : _ _	
10 hours post-dose		_ _ : _ _	
10.5 hours post-dose		_ _ : _ _	
11 hours post-dose		_ _ : _ _	

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.
Site: X X X	Subject Number: 0	Subject Initials:

BLOOD SAMPLE & DOSE LOG: Period 1 Continued

Sampling Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	Comments
12 hours post-dose	20	:	
16 hours post-dose	20	:	
20 hours post-dose	20	:	
24 hours post-dose	20	:	
30 hours post-dose	20	:	
36 hours post-dose		:	
48 hours post-dose	20	:	
60 hours post-dose		:	
72 hours post-dose	20	:	

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials
X X X	0	

IMPAIRMENT EVALUATION: Period 1

Date and time of Evaluation: 2 0 (d d/m m m/ y y y y) : (24 hr clock)

NOTE: A response of **Yes** to any of the following symptoms must be documented on the Adverse Events page.

Symptoms	No (X)	Yes (X)	Comments
Lightheadedness	☐	☐	
Dizziness	☐	☐	
Sedation	☐	☐	
Confusion	☐	☐	
Visual Disturbances	☐	☐	
Weakness	☐	☐	
Uncoordinated Muscle Movement	☐	☐	

Date/Time of release from the study site: 2 0 (d d/m m m/ y y y y) : (24 hr clock)

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Site	Subject Number	Subject Initials
X X X	0	

NALTREXONE DOSING: Period 2

Dosing Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	
12 hours prior to dosing	2 0	:	
12 hours post dosing	2 0	:	
24 hours post dosing	2 0	:	
36 hours post dosing		:	

Note: Time of 0 hr dosing is reflected on Blood Sample & Dose Log page.

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials	NOTE: Repeated out-of-range vital signs that do not return to normal values are considered AEs and should be documented on the Adverse Events page.
X X X	0		

VITAL SIGNS: Period 2

Observation Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	Blood Pressure (mmHg)		Pulse Rate (bpm)	Respiratory Rate (breaths/min)	Oxygen Saturation (%)
			Systolic	Diastolic			
12 hours pre-dose	2 0	:					
11 hours pre-dose		:					
Pre-dose	2 0	:					
1 hour post-dose		:					
1.5 hours post-dose		:					
2.5 hours post-dose		:					
4.5 hours post-dose		:					
6.5 hours post-dose		:					
8.5 hours post-dose		:					
10.5 hours post-dose		:					
12 hours post-dose		:					
13 hours post-dose		:					

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials	NOTE: Repeated out-of-range vital signs that do not return to normal values are considered AEs and should be documented on the Adverse Events page.
X X X	0		

VITAL SIGNS: Period 2 Continued

Observation Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	Blood Pressure (mmHg)		Pulse Rate (bpm)	Respiratory Rate (breaths/min)	Oxygen Saturation (%)
			Systolic	Diastolic			
14 hours post-dose	2 0	:					
16 hours post-dose	2 0	:					
24 hours post-dose	2 0	:					
25 hours post-dose	2 0	:					
36 hours post-dose		:					
37 hours post-dose	2 0	:					
48 hours post-dose	2 0	:					
60 hours post-dose		:					
72 hours post-dose	2 0	:					

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials	
X X X	0		**NOTE: Repeated out-of-range vital signs that do not return to normal values are considered AEs and should be documented on the Adverse Events page.**

Were any additional/repeat Vital Signs done during Period 2? No ☐ Yes ☐ If Yes, record below.

Observation Time Repeated	Date (d d / m m m / y y y y)	Time (24 hr clock)	Blood Pressure (mmHg)		Pulse Rate (bpm)	Respiratory Rate (breaths/min)	Oxygen Saturation (%)	Comments
			Systolic	Diastolic				
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials	
X X X	0		**NOTE: Repeated out-of-range vital signs that do not return to normal values are considered AEs and should be documented on the Adverse Events page.**

SUPPLEMENTAL ADDITIONAL/REPEAT VITAL SIGNS: Period 2

Observation Time Repeated	Date (d d / m m m / y y y y)	Time (24 hr clock)	Blood Pressure (mmHg)		Pulse Rate (bpm)	Respiratory Rate (breaths/min)	Oxygen Saturation (%)	Comments
			Systolic	Diastolic				
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						
		:						

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials
X X X	0	

MEAL CONSUMPTION RECORD: Period 2

Did subject consume the entire breakfast?

☐ No (If No, the subject is to be dropped.)

☐ Yes

Breakfast Start Time: __ __ : __ __ (24 hr clock)

Breakfast End Time: __ __ : __ __ (24 hr clock)

BLOOD SAMPLE & DOSE LOG: Period 2

Treatment Assignment:

☐ Treatment A

☐ Treatment B

Dosing Date: __ __ / __ __ / 2 0 __ __ (d d / m m m / y y y y)

Time: __ __ : __ __ (24 hr clock)

Note: Dosing date and time will be for treatment dosing as well as 0 hour Naltrexone dosing.

Sampling Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	Comments
Pre-Dose	__ __ / __ __ / 2 0 __ __	__ __ : __ __	
0.75 hours post-dose		__ __ : __ __	
1.5 hours post-dose		__ __ : __ __	
2.5 hours post-dose		__ __ : __ __	
3.5 hours post-dose		__ __ : __ __	
4.5 hours post-dose		__ __ : __ __	
5.5 hours post-dose		__ __ : __ __	
6.5 hours post-dose		__ __ : __ __	
7.5 hours post-dose		__ __ : __ __	
8.5 hours post-dose		__ __ : __ __	
9.5 hours post-dose		__ __ : __ __	
10 hours post-dose		__ __ : __ __	
10.5 hours post-dose		__ __ : __ __	
11 hours post-dose		__ __ : __ __	

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.
Site: X X X	Subject Number: 0	Subject Initials:

BLOOD SAMPLE & DOSE LOG: Period 2 Continued

Sampling Time	Date (d d / m m m / y y y y)	Time (24 hr clock)	Comments
12 hours post-dose	20	:	
16 hours post-dose	20	:	
20 hours post-dose	20	:	
24 hours post-dose	20	:	
30 hours post-dose	20	:	
36 hours post-dose		:	
48 hours post-dose	20	:	
60 hours post-dose		:	
72 hours post-dose	20	:	

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.

Site	Subject Number	Subject Initials
X X X	0	

IMPAIRMENT EVALUATION: Period 2

Date and time of Evaluation: 2 0 (d d/m m m/ y y y y) : (24 hr clock)

NOTE: A response of **Yes** to any of the following symptoms must be documented on the Adverse Events page.

Symptoms	No (X)	Yes (X)	Comments
Lightheadedness	☐	☐	
Dizziness	☐	☐	
Sedation	☐	☐	
Confusion	☐	☐	
Visual Disturbances	☐	☐	
Weakness	☐	☐	
Uncoordinated Muscle Movement	☐	☐	

Date/Time of release from the study site: 2 0 (d d/m m m/ y y y y) : (24 hr clock)

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Subject Identification	STUDY # 850	Mallinckrodt Inc.
Site: X X X	Subject Number: 0	Subject Initials:

PHYSICAL EXAMINATION: Exit

Date and time of Exam: 2 0 (d d/m m m/y y y y) : (24 hr clock)

Were any changes noted from Screening Physical exam?
No ☐ Yes ☐

NOTE: Any clinically significant changes in physical exam should be documented on the Adverse Events page. Please check and complete the requested information **only for those** observations which have changed from the screening assessment.

Observations	Briefly Describe Change from Screening	Clinically Significant?
General Appearance		No ☐ Yes ☐
Skin		No ☐ Yes ☐
HEENT		No ☐ Yes ☐
Neck		No ☐ Yes ☐
Chest		No ☐ Yes ☐
Heart		No ☐ Yes ☐
Abdomen/Pelvis		No ☐ Yes ☐
Extremities		No ☐ Yes ☐
Neurological		No ☐ Yes ☐

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254 MNKOI 0006877257

Site	Subject Number	Subject Initials
X X X	0	

SUBJECT DISPOSITION

Did the subject complete the study? No ☐ Yes ☐

If **No**, date discontinued:

d d / m m m / y y y y

If No, specify the primary reason for termination of the subject's participation below:

☐ 1. Adverse Event (check one box below)

☐ Subject Decision ☐ Investigator Decision ☐ Sponsor Decision

☐ 2. Lost to follow-up

☐ 3. Died on d d / m m m / y y y y

☐ 4. The subject requested to be withdrawn from the study.
Specify reason: _____

_____

☐ 5. Protocol violation(s)
Specify reason: _____

_____

☐ 6. Other: _____

_____

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254

Site	Subject Number	Subject Initials
X X X	0	

CLINICAL COURSE

Please provide additional pertinent clinical information and observations not reflected in this case report form in the space provided below. If additional space is required, attach typed pages.

CRF Page	Comment

I have reviewed this case report form and find the data to be complete and accurate to the best of my knowledge.

Signature _____ Date _____

Principal Investigator

(d d / m m m / y y y y)

Source: https://www.industrydocuments.ucsf.edu/docs/gpff0254